MINUTES OF 321ST MEETING OF REGISTRATION BOARD HELD ON 20-22ND SEPTEMBER, 2022

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321st meeting of Registration Board was held on 20-22nd September, 2022 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad. The meeting was chaired by Dr. Obaidullah, Chairman Registration Board DRAP. The meeting started with recitation of the Holy Verses.

The Board decided to co-opt Dr. Shabnum Firdous, Secretary / Registrar, Pakistan Veterinary Medical Council, as member under Rule 24 (6) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 of the Drugs Act, 1976, in order to facilitate the Registration Board regrading opinion on the applications for registration of veterinary products.

Following members attended the meeting:

1.	Ch. Zeeshan Nazir Bajar, Additional Director (BE&R/PE&R), DRAP.	Member/ Secretary
2.	Lt.Gen.(R) Prof. Dr. Karamat A. Karamat (HI-M.SI-M), Former Surgeon General Pakistan.	Member
3.	Maj. Gen. (R) Dr. Tahir Mukhtar Sayed, Inspector General (Hospitals), Fauji Foundation, Rawalpindi	Member
4.	Dr. Qurban Ali, Ex-Director General, National Veterinary Laboratories, Islamabad	Member
5.	Dr. Noor us Saba, Director, Biological Evaluation & Research Division, DRAP	Member
6.	Dr. Muhammad Akram, Animal Husbandry Commissioner, M/o NFS&R	Co-opted Member
7.	Dr. Ali Ahmad Agha, Director, DTL, Quetta	Member
8.	Muhammad Hafeez ur Rehman, DTL, Rawalpindi	Member
9.	Mr. Muhammad Aslam, Deputy Draftsman-I, Ministry of law & Justice, Islamabad.	Member
10.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO	
11.	Dr. Imran Khan, Director, DTL, Peshawar	Member
12.	Mr. Akhtar Abbas Khan, Representative of QA&LT Division	Member
13.	Mr. Abdullah, Representative of Division of MD&MD	Member
14.	Dr. Shabnum Firdous, Secretary / Registrar, Pakistan Veterinary Medical Council	Co-opted Member

Mr. Nadeem Alamgir (Pharma Bureau), Hafiz Muhammad Azeem, Mr. Hamid Raza & Mr. Jalal-ud-Din (PPMA) and Mr. Ziaulhaq & Mr. Amir (PCDA) attended the meeting as observers.

Director, BE&R was assisted by respective Additional Director and Assistant Directors for presentation of the agenda.

Item No. I: Confirmation of Minutes of 320th meetings of Registration Board.

320th meeting of Registration Board was held on 20-22nd September, 2022. The draft minutes of Registration Board were circulated among the members of Board on 16th September, 2022 for perusal/approval/comments (if any) within five days. All members agreed the draft minutes on 21st September, 2022 during 321st meeting of Registration Board.

Accordingly, fair minutes were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 320th meeting of Registration Board were circulated among concerned divisions/sections for implementation of decisions.

Decision: Registration Board confirmed the minutes of 320th meeting of Registration Board.

Item No. II Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
1.	Mr. Farooq Aslam	Evaluator PEC-I
2.	Mr. Ammar Ashraf Awan	Evaluator PEC-II
3.	Mr. Muhammad Haseeb Tariq	Evaluator PEC-III
4.	Mst.Farzana Raja	Evaluator PEC-IV
5.	Mst. Iqra Aftab	Evaluator PEC-V
6.	Mr. Muhammad Umar Latif	Evaluator PEC-VI
7.	Dr. Sidra Khalid	Evaluator PEC-VII
8.	Dr. Hanif Ullah	Evaluator PEC-IX
9.	Dr. Farhadullah	Evaluator PEC-XI
10.	Mr. Shahid Nawaz	Evaluator PEC-XIII
11.	Mr. Ahsan Hafiz	Evaluator PEC-XIV
12.	Mst. Saima	Evaluator PEC-XV
13.	Mr. Akbar Ali	Evaluator PEC-XVI
14.	Mr. Zia Ullah	Evaluator PEC-XVII
15.	Mr. Muneeb Ahmed Cheema	Evaluator PEC-XVIII
16.	Mr. Sarfraz Nawaz	Evaluator PE&R

1.	Name, address of Applicant / Marketing Authorization Holder	M/s News Pharma Plot 42, Sundar Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s News Pharma Plot 42, Sundar Industrial Estate Lahore
	Details of Drug Manufacturer License	DML No.: Address: M/s News Pharma Plot 42, Sundar Industrial Estate Lahore Validity: 18/02/2018 valid till 5 year
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6138 dated: 7 March 2022
	Details of fee submitted	PKR 30,000/-: dated 02-03-2022
	The proposed proprietary name / brand name	Newsfen 100 mg / 5 mL Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 mL contains: Ibuprofen .... 100 mg
	Pharmaceutical form of applied drug	Clear sweet strawberry flavored homogeneous oral suspension filled in amber glass bottle sealed with aluminium cap and packed in printed unit cartons.
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	Proposed Pack size	1 ×60 mL, 1 x 90 mL, 1x120 mL, 1x 400 mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ibuprofen 100 mg / 5 mL suspension by M/s Pinewood healthcare UK (MHRA Approved)
	For generic drugs (me-too status)	Brufen Suspension by Abbott Laboratories Reg. No. 004595
	GMP status of the Finished product manufacturer	New additional section of Oral Liquid Syrup approved on: 12-11-2021
	Name and address of API manufacturer.	Zenith Chemical Industries (Pvt.) Limited. Moaza Dhondhay, Jia Bagga, Raiwind Road Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability

		studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ibuprofen is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity F & related substances (impurities A J, N), unspecified & total impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(ZIBU11-001ZIBU11-002, ZIBU11-003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Brufen 100 mg/5 mL Susp. By M/s Abbott Laboratories by performing quality tests (Identification, Assay, Uniformity of dosage unit and determination of 4 - Isobutyl acetophenone (Ibuprofen impurity E). CDP – Not applicable
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Zenith Chemical Industries (Pvt.) Limited. Moaza Dhondhay, Jia Bagga, Raiwind Road Lahore
API Lot No.	ZIBU21-029
Description of Pack (Container closure system)	Clear sweet strawberry flavored homogeneous oral suspension filled in amber glass bottle sealed with aluminium cap and packed in printed unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T-01	T-02	T-03
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-09-2021	08-09-2021	08-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 141/2019-DRAP (AD 813875-228) dated 22-05-2019 issued by DRAP
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit Trail submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

analytical procedure of drug substance from drug substance manufacturer is missing

S. No	Sections	Observations/Deficiencies/ Short-comings	Response
1.	2.3.R.1.1	method mentioned in BMR's is not same mentioned in section 3.2.P.2.3 and 3.2.P.3.5. Clarification is required.	Critical parameters were only mentioned in BMR both 3.2.P.2.3 and 3.2.P.3.5 have been revised and attached
2.		Batch size 100 bottles mentioned while in stability sheets and COA's 45 bottles mentioned.	The actual batch size was 45 bottles, 100 was mentioned by mistake
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance is required.	Submitted
4.	3.2.S.4.3	In B.P and as per your method Assay is carried out by titration method while Verification studies are conducted by HPLC. Clarification is required.	Verification studies are conducted by titration method is provided
5.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided	Provided
6.	3.2.P.4.4	The copies of complete analysis of at least two batches shall be provided.	Complete analysis of at least two batches is provided

Decision: Approved.

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

2.	Name, address of Applicant / Marketing Authorization Holder	M/s News Pharma Plot 42, Sundar Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s News Pharma Plot 42, Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6139 dated 07 March 2022
	Details of fee submitted	PKR 30,000/-: dated 02-03-2022 (77876249)
	The proposed proprietary name / brand name	Newsfen DS 200 mg / 5 mL Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 mL contains: Ibuprofen .... 200 mg
	Pharmaceutical form of applied drug	Clear sweet Orange flavored homogeneous oral suspension filled in amber pet bottle sealed with aluminium cap and packed in printed unit carton.
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	Proposed Pack size	1 ×60 mL, 1 x 90 mL, 1x120 mL, 1x 400 mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ibuprofen Twelve Plus Pain Relief 200mg/5ml oral suspension by M/s Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road Petersfield Hampshire GU32 3QG United Kingdom (MHRA Approved)
	For generic drugs (me-too status)	Brufen Suspension 200 mg/5 mL by Abbott Laboratories Reg. No. 070851
	GMP status of the Finished product manufacturer	New additional section of Oral Liquid Syrup approved on: 12-11-2021
	Name and address of API manufacturer.	Zenith Chemical Industries (Pvt.) Limited. Moaza Dhondhay, Jia Bagga, Raiwind Road Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ibuprofen is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity F & related substances (impurities A J, N), unspecified & total impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(ZIBU11-001ZIBU11-002, ZIBU11-003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Brufen 200 mg/5 mL Susp. By M/s Abbott Laboratories by performing quality tests (Identification, Assay, Uniformity of dosage unit and determination of 4 - Isobutyl acetophenone (Ibuprofen impurity E). CDP – Not applicable
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Zenith Chemical Industries (Pvt.) Limited. Moaza Dhondhay, Jia Bagga, Raiwind Road Lahore
API Lot No.	ZIBU21-029
Description of Pack (Container closure system)	Clear sweet Orange flavored homogeneous oral suspension filled in amber pet bottle sealed with aluminium cap and packed in printed unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	45 Bottles	45 Bottles	45 Bottles
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-09-2021	08-09-2021	08-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 141/2019-DRAP (AD 813875-228) dated 22-05-2019 issued by DRAP
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit Trail submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Response
1.	2.3.R.1.1	method mentioned in BMR's is not same mentioned in section 3.2.P.2.3 and 3.2.P.3.5. Clarification is required.	Critical parameters were only mentioned in BMR both 3.2.P.2.3 and 3.2.P.3.5 have been revised and attached
2.		Batch size 100 bottles mentioned while in stability sheets and COA's 45 bottles mentioned.	The actual batch size was 45 bottles, 100 was mentioned by mistake
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance is required.	Submitted
4.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided	Provided
5.	3.2.P.4.4	The copies of complete analysis of at least two batches shall be provided.	complete analysis of at least two batches is provided

Decision: Approved.

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

3.	Name, address of Applicant / Marketing Authorization Holder	M/s Sayyed Pharmaceutical (Pvt) Ltd,Hattar.
	Name, address of Manufacturing site.	Plot no 67/2,Phase 3,Industrial estate, hattar, Haripur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9917 dated 19/04/2022
	Details of fee submitted	PKR 30,000/-: dated 05/04/2022
	The proposed proprietary name / brand name	Brosyd 3mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Bromazepam…….3mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Benzodiazepine
	Reference to Finished product specifications	Mgr. Specs
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lexotan 3mg tablet by ROCHE. TGA; Australia Approved
	For generic drugs (me-too status)	Calmease 3mg tablet by Wilsons.
	GMP status of the Finished product manufacturer	New Section approved. GMP inspection conducted on 23 june 2021
	Name and address of API manufacturer.	M/s Cambrex Proformaco Milano Via Curiel 34-20067 Paullo ML-Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related

		substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Comparator that is LExotanil 3mg tablet by Martin Dow Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Lexotanil 3mg tablet by Martin Dow Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s Cambrex Proformaco Milano Via Curiel 34-20067 Paullo ML-Italy.		
API Lot No.	871120		
Description of Pack (Container closure system)	Alu-Pvc blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-01	Trial-02	
Batch Size	5000 tab	5000 tab	
Manufacturing Date	12-2021	12-2021	
Date of Initiation	02-12-2021	02-12-2021	
No. of Batches	02		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Alprazolam 0.25mg,0.5mg and 1mg Tablet. Clonazepam 0.5mg and 2mg Tablet.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	API manufacturer is approved by the regulatory authority of Italy which is a reference regulatory authority.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Invoice No 1000000757 dated 28-04-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches are supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S No	Section #.	Deficiencies	Reply
1.	1.6.5	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin is needed as the provided one is valid till January 2021	The GMP compliance certificate # IT-API/57/H/2022 issued by AIFA valid for 3 years from 01/10/2021
2.	3.2.P.5	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice for the procurement of API with approval from DRAP is provided
3.	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary / secondary reference standard including source and lot number is provided
4.	3.2.P.8.2	Provides stability study protocols	Submitted
5.		• As per relevant guidelines & structure of Form 5F, Comparative Dissolution profile and comparative assay has to be performed at the time of formulation development, while according to your submitted data, Comparative Dissolution profile studies and comparative assay have been performed after commencing stability studies. Justification shall be submitted.	As analysis of formulation development was finished before two days of CDP end date, that's why that date on which formulation development analysis was finished, was considered as initial stability date

Decision: Approved with Innovator's specifications.

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

4.	Name, address of Applicant / Marketing Authorization Holder	M/s MedAsia Pharmaceutical (Pvt) Ltd. Plot #7 Nowshera industrial estate Risalpur KPK Pakistan.
	Name, address of Manufacturing site.	M/s MedAsia Pharmaceutical (Pvt) Ltd. Plot #7 Nowshera industrial estate Risalpur KPK Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on 2 8/12/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 13-01-2022 which specifies Oral Dry powder suspension (general) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No: 5413 25/02/2022
	Details of fee submitted	PKR 30,000/-: 25/02/2022 (#255776532)
	The proposed proprietary name / brand name	**Antra 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Omeprazole as Enteric Coated Pellets…20mg
	Pharmaceutical form of applied drug	Dark Blue color cap and light blue color body containing off white color Enteric Coated pellets
	Pharmacotherapeutic Group of (API)	PPI (Proton pump Inhibitor)
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole capsule is USFDA Approved
	For generic drugs (me-too status)	Getz Pharma (Risk 20 mg Capsule)
	GMP status of the Finished product manufacturer	New license granted on 11/11/2021 Tablet General, Capsule General& General Dry Suspension section approved.
	Name and address of API manufacturer.	M/S Vision pharmaceuticals Plot No22,23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Omeprazole Capsule is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and

		controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (OMP073, OMP074, OMP075)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Risek 20 mg Capsule by Getz Pharma (# C04005) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Risk 20 mg capsule by Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of APIs	**Omeprazole** Vision Pharmaceuticals Plot # 22-23, industrial triangle Kahuta road Islamabad		
API Lot No.	**Omeprazole** OMP860		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	028	41	47
Batch Size	35106	35106	35106
Manufacturing Date	11-2018	11-2018	1-2019
Date of Initiation	20-11-2018	20-11-2018	01-01-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.326/2019-addl.Dir (QA&LT-I) issued by Govt of Pakistan ministry of Health valid till 10/02/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of Import).	Omeprazole pallets are locally procured from vision pharma Islamabad
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with Chromatograms, raw data sheets, COAs and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted 21 CFR evidence and audit trail reports of product testing.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks OF Evaluator:

S. No	Observations/Deficiencies/ Short-comings	Reply
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.326/2019-addl.Dir (QA&LT-I) issued by Govt of Pakistan ministry of Health valid till 10/02/2022 is provided
2.	Provide evidence of purchase including commercial invoice of the drug substance.	Invoice document #302848 from M/S vision pharma is provided
3.	Provide copy of BMR of the stability batches	Provided
4.	Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.	COA of reference standard which is actually used in the analysis of drug substance in section is provided
5.	Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia**.**	Pharmaceutical Equivalence have been established against the brand leader that is Risek 20 mg Capsule by Getz Pharma (# C04005) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Risk 20 mg capsule by Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range. All the results are provided which concludes that the developed formulation of omeprazole 20 mg capsule have comparable product quality and performance profile with that of comparator product

6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Compliance Record of HPLC software 21CFR & audit trail is provided
7.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature & humidity monitoring of stability chambers is provided

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of CDP and pharmaceutical equivalence studies, performed against the innovator's drug product i.e., Losec capsule 20mg.**

5.	Name, address of Applicant / Marketing Authorization Holder	M/s MedAsia Pharmaceutical (Pvt) Ltd. Plot #7 Nowshera industrial estate Risalpur KPK Pakistan.
	Name, address of Manufacturing site.	M/s MedAsia Pharmaceutical (Pvt) Ltd. Plot #7 Nowshera industrial estate Risalpur KPK Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on 8/12/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 13-01-2022 which specifies Oral Dry powder suspension (general) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No: 12605 24/ May/2022
	Details of fee submitted	PKR 30,000/-: 25/04/2022 (#7178762428)
	The proposed proprietary name / brand name	**Antra 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Omeprazole as Enteric Coated Pellets…40mg
	Pharmaceutical form of applied drug	Dark Blue color cap and light blue color body containing off white color Enteric Coated pellets
	Pharmacotherapeutic Group of (API)	PPI (Proton pump Inhibitor)
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole capsule is USFDA Approved

	For generic drugs (me-too status)	Getz Pharma (Risk 40 mg Capsule)
	GMP status of the Finished product manufacturer	New license granted on 11/11/2021 Tablet General, Capsule General& General Dry Suspension section approved.
	Name and address of API manufacturer.	M/S Vision pharmaceuticals Plot No22,23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Omeprazole Capsule is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (OMP073, OMP074, OMP075)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Risek 40 mg Capsule by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Risk 40 mg Capsule Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range..

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of APIs	**Omeprazole** Vision Pharmaceuticals Plot # 22-23, industrial triangle Kahuta road Islamabad		
API Lot No.	**Omeprazole** OMP 812		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	030	46	451
Batch Size	21276	21276	21276
Manufacturing Date	11-2018	11-2018	05-2019
Date of Initiation	25-11-2018	28-11-2018	05-01-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.326/2019 issued by Govt of Pakistan ministry of Health valid till 10/02/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of Import).	Omeprazole pallets are locally procured from vision pharma Islamabad
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with Chromatograms, raw data sheets, COAs and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted 21 CFR evidence and audit trail reports of product testing.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks OF Evaluator:

S. No	Observations/Deficiencies/ Short-comings	Reply
1.	Submit details including Batch number, manufacturing and expiry date of the comparator product against which pharmaceutical equivalence as well as CDP studies were conducted.	Copy of GMP certificate No. F.326/2019-addl.Dir (QA&LT-I) issued by Govt of Pakistan ministry of Health valid till 10/02/2022 is provided

2.	Provide evidence of purchase including commercial invoice of the drug substance.	Invoice document #302848 from M/S vision pharma is provided
3.	Provide copy of BMR of the stability batches	Provided
4.	Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.	COA of reference standard which is actually used in the analysis of drug substance in section is provided
5.	Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia**.**	Pharmaceutical Equivalence have been established against the Risek 40 mg Capsule by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Risk 20 mg capsule by Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range. All the results are provided which concludes that the developed formulation of omeprazole 40 mg capsule have comparable product quality and performance profile with that of comparator product
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Compliance Record of HPLC software 21CFR & audit trail is provided
7.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature & humidity monitoring of stability chambers is provided

Decision: Approved.

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

6.	Name, address of Applicant / Marketing Authorization Holder	M/s Medasia Pharmaceuticals Nawashera Industrial Estate Risalpur KPK
	Name, address of Manufacturing site.	M/s Medasia Pharmaceuticals Nawashera Industrial Estate Risalpur KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Diary # 12607 dated: 24 May 2022
	Details of fee submitted	PKR 30,000/-: dated 07/05/2021
	The proposed proprietary name / brand name	Esasia 20 mg Capsule

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeprazole (Enteric Coated pellets)….20 mg
	Pharmaceutical form of applied drug	Sky Blue color cap and white color body containing off white color Enteric Coated pellets
	Pharmacotherapeutic Group of (API)	PPI (Proton pump Inhibitor)
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXIUM 20 mg CAPSULES by M/s AstraZeneca Pharmaceuticals, USFDA Approved
	For generic drugs (me-too status)	Getz Pharma (Nexum 20 mg Capsule)
	GMP status of the Finished product manufacturer	New license granted on 11/11/2021 Tablet General, Capsule General& General Dry Suspension section approved.
	Name and address of API manufacturer.	M/S Vision pharmaceuticals Plot No22,23,Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (EMZ044440, EMZ044440, EMZ044440)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nexum by Getz pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nexum 20 mg capsule by Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/S Vision pharmaceuticals		
API Lot No.	EMZ046082		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	029	44	45
Batch Size	34900	34900	34900
Manufacturing Date	11-2018	12-2018	12-2018
Date of Initiation	22-11-2018	18-12-2018	19-12-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.326/2019 issued by Govt of Pakistan ministry of Health valid till 10/02/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Esomeprazole pallets are locally procured from vision pharma Islamabad
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with Chromatograms, raw data sheets, COAs and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted 21 CFR evidence and audit trail reports of product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

S. No	Observations/Deficiencies/ Short-comings	Reply
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.326/2019-addl.Dir (QA&LT-I) issued by Govt of Pakistan ministry of Health valid till 10/02/2022 is provided
2.	Provide evidence of purchase including commercial invoice of the drug substance.	Invoice document #302848 from M/S vision pharma is provided
3.	Provide copy of BMR of the stability batches	Provided
4.	Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.	COA of reference standard which is actually used in the analysis of drug substance in section is provided
5.	Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia**.**	Pharmaceutical Equivalence have been established against the brand leader that is Nexum 20 mg Capsule by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nexum 20 mg Capsule by Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range. All the results are provided which concludes that the developed formulation of esomeprazole 20 mg capsule have comparable product quality and performance profile with that of comparator product
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Compliance Record of HPLC software 21CFR & audit trail is provided
7.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature & humidity monitoring of stability chambers is provided

Decision: Decision: Approved.

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

7.	Name, address of Applicant / Marketing Authorization Holder	M/s Medasia Pharmaceuticals Nawashera Industrial Estate Risalpur KPK
	Name, address of Manufacturing site.	M/s Medasia Pharmaceuticals Nawashera Industrial Estate Risalpur KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Diary # 12606 dated: 24 May 2022
	Details of fee submitted	PKR 30,000/-: dated 07/05/2021
	The proposed proprietary name / brand name	Esasia40 mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeprazole (Enteric Coated pellets) ….40 mg
	Pharmaceutical form of applied drug	Sky Blue color cap and white color body containing off white color Enteric Coated pellets
	Pharmacotherapeutic Group of (API)	PPI (Proton pump Inhibitor)
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXIUM 40 mg CAPSULES by M/s AstraZeneca Pharmaceuticals, USFDA Approved
	For generic drugs (me-too status)	Getz Pharma (Nexum 40 mg Capsule)
	GMP status of the Finished product manufacturer	New license granted on 11/11/2021 Tablet General ,Capsule General& General Dry Suspension section approved.
	Name and address of API manufacturer.	M/S Vision pharmaceuticals Plot No22,23,Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (EMZ044440, EMZ044440, EMZ044440)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nexum 40 mg capsule by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nexum 40 mg capsule by Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA			
Manufacturer of API	M/S Vision pharmaceuticals		
API Lot No.	EMZ046082		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	055	056	057
Batch Size	21500	21500	21500
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	08-01-2019	09-01-2019	10-01-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.326/2019 issued by Govt of Pakistan ministry of Health valid till 10/02/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Esomeprazole pallets are locally procured from vision pharma Islamabad
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with Chromatograms, raw data sheets, COAs and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted 21 CFR evidence and audit trail reports of product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)
Remarks of Evaluator:		

S. No	Observations/Deficiencies/ Short-comings	Reply
1.	Submit details including Batch number, manufacturing and expiry date of the comparator product against which pharmaceutical equivalence as well as CDP studies were conducted.	Copy of GMP certificate No. F.326/2019-addl.Dir (QA&LT-I) issued by Govt of Pakistan ministry of Health valid till 10/02/2022 is provided
2.	Provide evidence of purchase including commercial invoice of the drug substance.	Invoice document #302848 from M/S vision pharma is provided
3.	Provide copy of BMR of the stability batches	Provided
4.	Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.	COA of reference standard which is actually used in the analysis of drug substance in section is provided
5.	Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia**.**	Pharmaceutical Equivalence have been established against the brand leader that is Nexum 40 mg Capsule by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nexum 40 mg Capsule by Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range. All the results are provided which concludes that the developed formulation of esomeprazole 40 mg capsule have comparable product quality and performance profile with that of comparator product
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Compliance Record of HPLC software 21CFR & audit trail is provided
7.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature & humidity monitoring of stability chambers is provided

Decision: Approved.

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

Case no. 02 Registration applications of drugs for which stability study data is submitted Registration applications for Form 5F

c) Form 5F (Human)

8.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited,7-Jail Road, Quetta
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited,7-Jail Road, Quetta
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26933 dated 29/09/2021
	Details of fee submitted	PKR 30,000/-: dated 13/09/2021 (#512065708279)
	The proposed proprietary name / brand name	Zaroxetine Tablet 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paroxetine HCl Hemihydrate, USP eq. to Paroxetine …… 20mg
	Pharmaceutical form of applied drug	White, Oblong Biconvex FCT with R1 on one side.
	Pharmacotherapeutic Group of (API)	Selective Serotonin-Reuptake Inhibitors (SSRIs) (Anti-Depressant)
	Reference to Finished product specifications	USP
	Proposed Pack size	3×10's (30's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	AG-PAROXETINE Tablet 20mg by M/s Angita Pharma Inc. HEALTH CANADA Approved.
	For generic drugs (me-too status)	Pronitron Tablet 20mg by Nabiqasim Industries (Pvt.) Ltd. , Reg. No. 07990
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Xunqiao, Linhai 317024, Zhejiang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paroxetine Hydrochloride Hemihydrate is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related

		substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Accelerated Time:** C5320-09-001, C5320-09-002, C5320-09-003 **Real Time:** 5320-14-003, 5320-14-004, 5320-14-005
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Seroxat Tablets 20mg** by **GlaxoSmithKline Pharmaceutical S.A** by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is **Seroxat Tablets 20mg** by **GlaxoSmithKline Pharmaceutical S.A** in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Xunqiao, Linhai 317024, Zhejiang, China		
API Lot No.	5301-20-013		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	10000 Tablets	10000 Tablets	10000 Tablets
Manufacturing Date	09-2020	09-2020	09-2020

Date of Initiation	10-2020	10-2020	10-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Applicable as it is non-inspection product
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20180073 issued by CFDA valid till 25/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	ADC Invoice No: HH20201310, 11-June-2020 is submitted wherein the permission to import API (Paroxetine Hydrochloride) for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		

Decision: Approved.

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

9.	Name, address of Applicant / Marketing Authorization Holder	M/s Relizon Pharmaceuticals Plot No. 118 Sundar Industrial estate Lahore
	Name, address of Manufacturing site.	M/s Relizon Pharmaceuticals Plot No. 118 Sundar Industrial estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24363 dated 03/09/2021
	Details of fee submitted	PKR 30,000/-: dated 27/07/2021
	The proposed proprietary name / brand name	Azith 250mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin as Dihydrate ……250mg.
	Pharmaceutical form of applied drug	Brilliant Blue oblong shaped film coated tablets having break line on one side and engraved “

		relizon'' on other side. Packed in ALU-ALU blister.
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×6's & 1×10's. (As per SRO)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azith 250mg tablet by M/s Zetamax, USFDA Approved.
	For generic drugs (me-too status)	Zetamax 250mg Tablet by M/s Pfizer Pharmaceuticals, Reg. No. 82148
	GMP status of the Finished product manufacturer	cGMP granted on 10/06/2022 Tablet (General Tablet Capsule Dry Powder suspension) section approved.
	Name and address of API manufacturer.	M/s HEBEI Dongfeng Pharmaceutical Co., LTD. China
	Module-II (Quality Overall Summary)	Relizon Pharma has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Azithromycin Dihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 monthsAccelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AZ001, AZ002, AZ003).
	Module-III (Drug Product):	The Relizon Pharma has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Zetamax 250mg tablet by Pfizer Pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Azith 250mg tablet Tablet by Relizon

		Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s HEBEI Dongfeng Pharmaceutical Co., LTD. China.		
API Lot No.	AZ20200152		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×6's) (1x10's).As per SRO.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AZ001	AZ002	AZ003
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	05-06-2020	05-06-2020	08-06-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The Relizon Pharma has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HB18364705 issued by CFDA valid till 05/02/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.SE20N00417/DRAP-AD-CD (I&E) dated 10/03/2020 is submitted wherein the permission to import different APIs including Azithromycin Dihydrate for the purpose of test/analysis and stability studies is granted. • DHL No.GXPEW20046920 dated 22/04/2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S No	Deficiencies	Reply

1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	The API/ DML/GMP certificate # 11120190003 of HEBEI Dongfeng Pharmaceutical Co., LTD. China issued by China food and drug administration china valid till 13/1/2024
2.	Analytical Procedures (a) Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing)	Analytical Procedures and Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing is provided
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
5.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.SE20N00417/DRAP-AD-CD (I&E) dated 10/03/2020 is submitted wherein the permission to import different APIs including Azithromycin Dihydrate for the purpose of test/analysis and stability studies is granted.DHL No.GXPEW20046920 dated 22/04/2020

Decision: Approved.

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

10.	Name, address of Applicant / Marketing Authorization Holder	M/s Relizon Pharmaceuticals Plot No. 118 Sundar Industrial estate Lahore
	Name, address of Manufacturing site.	M/s Relizon Pharmaceuticals Plot No. 118 Sundar Industrial estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24362 dated 03/09/2021
	Details of fee submitted	PKR 30,000/-: dated 27/07/2021
	The proposed proprietary name / brand name	**Azith 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin as Dihydrate ……500mg.

	Pharmaceutical form of applied drug	Brilliant Blue oblong shaped film coated tablets having break line on one side and engraved " relizon'' on other side. Packed in ALU-ALU blister.
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×6's & 1×10's. (As per SRO)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azith 500mg tablet by M/s Zetamax, USFDA Approved.
	For generic drugs (me-too status)	Zetamax 500mg Tablet by M/s Pfizer Pharmaceuticals, Reg. No. 076685
	GMP status of the Finished product manufacturer	cGMP granted on 10/06/2022 Tablet (General Tablet Capsule Dry Powder suspension) section approved.
	Name and address of API manufacturer.	M/s HEBEI Dongfeng Pharmaceutical Co., LTD. China
	Module-II (Quality Overall Summary)	Relizon Pharma has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Azithromycin Dihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AZ001, AZ002, AZ003).
	Module-III (Drug Product):	The Relizon Pharma has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Zetamax 250mg tablet by Pfizer Pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Azith 250mg tablet Tablet by Relizon Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH

		6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s HEBEI Dongfeng Pharmaceutical Co., LTD. China.		
API Lot No.	AZ20200152		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×6's) (1x10's).As per SRO.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AZ004	AZ005	AZ006
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	05-06-2020	05-06-2020	08-06-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The Relizon Pharma has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HB18364705 issued by CFDA valid till 05/02/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.SE20N00417/DRAP-AD-CD (I&E) dated 10/03/2020 is submitted wherein the permission to import different APIs including Azithromycin Dihydrate for the purpose of test/analysis and stability studies is granted. • DHL No.GXPEW20046920 dated 22/04/2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S No	Deficiencies	Reply

1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	The API/ DML/GMP certificate # 11120190003 of HEBEI Dongfeng Pharmaceutical Co., LTD. China issued by China food and drug administration china valid till 13/1/2024
2.	Analytical Procedures (a) Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing)	Analytical Procedures and Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing is provided
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
5.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.SE20N00417/DRAP-AD-CD (I&E) dated 10/03/2020 is submitted wherein the permission to import different APIs including Azithromycin Dihydrate for the purpose of test/analysis and stability studies is granted.DHL No.GXPEW20046920 dated 22/04/2020

Decision: Approved.

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

11.	Name and address of manufacturer / Applicant	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Erlin-S 5/100 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid 6.48 Eq. to Ertugliflozin…5mg Sitagliptin Phosphate Monohydrate 128.5 mg Eq. to Sitagliptin…100mg"
	Diary No. Date of R& I & fee	Diary No. Date of R& I & fee Dy.No 4208 dated 08-04-2021 Rs.50,000/- Dated 21-2-2019 (0794087)
	Pharmacological Group	Anti-Diabetic (A10BK04), (A10BD24)
	Type of Form	Form-5D
	Finished product Specification	Innovator specifications
	Pack size & Demanded Price	As per SOP
	Approval status of product in Reference Regulatory Authorities	STEGLUJAN™ (ertugliflozin and sitagliptin) USFDA Approved with box warning.
	Me-too status	NA

	GMP status	GMP inspection dated 26-10-2021 showed that the firm was considered to be operating at an acceptable level of compliance with GMP standards.
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Erlin-S 5/100 mg Tablet		
Name of Manufacturer	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.		
Manufacturer of API	**Ertugliflozin as L-Pyroglutamic acid:** Shanghai Pharma group Changzhou kony Pharmaceuticals co., Ltd Daixi street Luoyang town Wujin district Changzhou, Jiangsu China is submitted **Sitagliptin Phosphate Monohydrate:** Zhejiang yonta pharmaceutical co LTD No 1 4th Donghai avenue Zhejiang provincial chemical and medical raw material base Linhai zone Linhai city Zhejiang province China		
API Lot No.	**Ertugliflozin L-Pyroglutamic Acid**: ETG20190101 **Sitagliptin Phosphate Monohydrate:** 1827-0001-19049		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 months Real Time: 0,3,6 months		
Batch No.	19PD-3057-03-T	19PD-3058-04-T	19PD-3059-05-T
Batch Size	2500	2500	2500
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	12-2019	12-2019	12-2019
No. of Batches	03		
Date of Submission	22-12-2020 (Dy. No.34038)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product Erli Plus XR Tablet 5/1000mg, 10/1000mg, 12.5/1000mg & 25/1000mg (Empagliflozin + Metformin HCl XR) which was conducted on 05th December, 2019 and were presented in 293rd meeting of Registration Board held on 6th -8th Jan, 2020. According to the report following points were confirmed. • Firm has 21 CFR compliant HPLC software. • Firm has audit trail reports available. • Firm possesses stability chambers with digital data loggers.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Ertugliflozin- LPGA:** Copy of COA of Ertugliflozin L-pyroglutamic acid eq to Ertugliflozin (L-Pyroglutamic acid) (Batch# ETG20190101)) from M/s Shangai Pharma

		Group Changzhou Kony Pharmaceutical Co., Ltd., Daixi Street, Louyang Town, Wujin District, Changzhou, Jiangsu 213105, China is submitted. Copy of COA from M/s PharmEvo (private) Limited is submitted. **Sitagliptin Phosphate:** Copy of COA of Sitagliptin Phosphate (Batch# 1827-0001-19049) from Zhejiang Yontai Pharmaceutical co. ltd-Donghai 4th Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province is submitted. Copy of COA (Batch# 1827-0001-19049) from M/s PharmEvo (private) Limited is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Provided
4.	Stability study data of API from API manufacturer	**Ertugliflozin:** Provided (The firm has submitted accelerated & real time stability studies for 3 batches (ETG20161201, ETG20161202, ETG20170101) at Real time: 30°C ± 2°C / 65% ± 5%RH and Accelerated: 40°C ± 2°C / 75% ± 5%RH) **Sitagliptin:** Provided (The firm has submitted accelerated & real time stability studies for 3 batches (1827-0001-18001, 1827-0001-18002, 1827-0001-18003) at Real time: 30°C ± 2°C / 65% ± 5%RH and Accelerated: 40°C ± 2°C / 75% ± 5%RH)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin:** Copy of GMP certificate (certificate No.JS20180935) issued to Shanghai pharma group Changzhou by CFDA. It is valid until 26/11/2023 **Sitagliptin:** cGMP certificate # ZJ20170014 issued by china food and drug administration to the manufacturer (Zheijiang Youngtai pharmaceuticals co ltd) and its valid till **3rd May 2022**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin** The firm has submitted copy of invoice for the purchase (1.2 kg) attested by Assistant Director DRAP, dated 7-1-2020 **Sitagliptin:** The firm has submitted copy of invoice for the purchase (500 kg) attested by Assistant Director DRAP, but commercial invoice was attested provided by Hangzhou biobounce technology co LTD
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:<table><tr><th>Batch no.</th><th>Batch Size</th><th>Mfg. Started</th></tr><tr><td>19PD-3057-03-T</td><td>2500</td><td>12-2019</td></tr><tr><td>19PD-3058-04-T</td><td>2500</td><td>12-2019</td></tr><tr><td>19PD-3059-05-T</td><td>2500</td><td>12-2019</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand Steglujan”.
The details are as follows:<table><tr><th>Feature</th><th>Reference Product</th><th>Product of PharmEvo</th></tr><tr><td>Brand Name</td><td>Steglujan Tablet 5mg/100mg</td><td>Erlin-S Tablet 5/100mg</td></tr><tr><td>Batch No.</td><td>T011927</td><td>19PD-3057-03-T</td></tr></table>Comparative dissolution studies have been performed in following mediums:
1. pH 1.2 HCl buffer
2. pH 4.5 Acetate buffer
3. pH 6.8 Phosphate buffer</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>The firm has submitted photocopy of Batch Manufacturing Record of three stability batches</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Provided</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Provided</td></tr>
</table>

REMARKS OF EVALUATOR [VII]

S No	Deficiency	Response
1.	Need valid GMP issued by the province as the current GMP certificate issued by Zheijang medical Centre for economic development is valid till 30-06-2021	Copy of DML# 20120015 issued by NMPA valid upto 31-05-2027 has been submitted.
2.	The GMP, quality control department analysis report and COA is from Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China. And on many documents including commercial invoice name is mentioned as Shanghai Pansopharma technology Co., Ltd. Jiangsu China. Provide the relationship.	The Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China is the manufacturer which might be confirmed by the submitted GMP whereas shanghai Pansopharm technology co Ltd is an exporter of Ertugliflozin. Declaration letter is provided.

3.	Commercial invoice of sitagliptin wasn't attested and provided by Hangzhou biobounce technology Co LTD not zheijang youngtai pharma. Clarification is needed	Commercial invoice of sitagliptin was attested and provided by Hangzhou biobounce technology Co LTD which is the exporter of sitagliptin. zheijang youngtai pharma co Ltd is the manufacturer of sitagliptin
4.	Reference of previous approval of applications with stability study data of the firm is needed	Submitted
5.	Certificate of analysis of API from both drug substance and drug product manufacturer	Certificate of analysis of API from both drug substance and drug product manufacturer were provided
6.	Record of comparative dissolution data is needed	Submitted

Decision: Approved with Innovator's specifications.

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

12.	Name and address of manufacturer / Applicant	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Erlin-M 7.5/1000 mg Tablet
	Composition	Each film coated tablet contains: 9.71 mg Ertugliflozin L-pyroglutamic acid (as Ertugliflozin) …….. 7.5 mg Metformin hydrochloride……..1000 mg
	Diary No. Date of R& I & fee	Diary No. Date of R& I & fee Dy.No 6452 dated 26 02-2021 Rs.50,000/- 4 march 2019) Anti-Diabetic (A10BK04), (A10BD24)
	Pharmacological Group	Anti-Diabetic (A10BK04), (A10BD24)
	Type of Form	Form-5D
	Finished product Specification	Innovator specifications
	Pack size & Demanded Price	As per SOP
	Approval status of product in Reference Regulatory Authorities	SEGLUROMET (ertugliflozin and Metformin) USFDA Approved
	Me-too status	NA
	GMP status	GMP inspection dated 26-10-2021 showed that the firm was considered to be operating at an acceptable level of compliance with GMP standards
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Erlin-M 7.5/1000 mg Tablet
Name of Manufacturer	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.
Manufacturer of API	**Ertugliflozin:**

	M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Daixi Street, Louyang Town, Wujin District, Changzhou, Jiangsu 213105, China. **Metformin HCl:** Smruthi Organics Limited, A-27, MIDC Chincholi, Tal-Mohol, Solapur 413255 Maharashtra State, India.		
API Lot No.	**Ertugliflozin L-Pyroglutamic Acid**: LPGA: ETG20190101 **Metformin:** MET-559/19		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 months Real Time: 0,3,6 months		
Batch No.	**19PD-3010-05-T**	**19PD-3011-06-T**	**19PD-3012-07-T**
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	16-2019	11-2019	11-2019
Date of Initiation	12-2019	12-2019	12-2019
No. of Batches	03		
Date of Submission	22-12-2020 (Dy. No.34038)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product Erli Plus XR Tablet 5/1000mg, 10/1000mg, 12.5/1000mg & 25/1000mg (Empagliflozin + Metformin HCl XR) which was conducted on 05th December, 2019 and were presented in 293rd meeting of Registration Board held on 6th -8th Jan, 2020. According to the report following points were confirmed. • Firm has 21 CFR compliant HPLC software. • Firm has audit trail reports available. • Firm possesses stability chambers with digital data loggers.

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Ertugliflozin- LPGA:** Copy of COA of Ertugliflozin L-pyroglutamic acid eq to Ertugliflozin (L-Pyroglutamic acid) (Batch# ETG20190101)) from M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Daixi Street, Louyang Town, Wujin District, Changzhou, Jiangsu 213105, China is submitted. Copy of COA from M/s PharmEvo (private) Limited is submitted. **Metformin HCl:** Copy of COA (Batch# MET-559/19) from Smruthi Organics Limited A-27, MIDC Chincholi, Tal- Mohol, Solapur 413255 Maharashtra State, India is submitted. Copy of COA (Batch# 1835) from M/s PharmEvo (private) Limited is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Provided
4.	Stability study data of API from API manufacturer	The firm has submitted accelerated & real time stability studies for 3 batches at Real time: 30°C ± 2°C / 65% ± 5% RH and Accelerated: 40°C ± 2°C / 75% ± 5%RH)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin-** LPGA: Copy of GMP (# JS20180935) for M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., China issued by China Food and Drug Administration of the People's Republic of China is submitted, valid up to 26-11-2023. **Metformin:** of Drug manufacturing license (License no. NEW-WHO-GMP/CERT/PD/86368/2019/11/30111) for Smruthi Organics Limited A-27, MIDC Chincholi, Tal-Mohol, Solapur 413255 Maharashtra State, India is submitted, valid up to 13-Nov-2022
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin** the firm has submitted copy of invoice for the purchase (1.2 kg) attested by Assistant Director DRAP, dated 7-1-2020 **Metformin:** Firm has submitted copy of commercial invoice specifying import of 3000 Kg metformin dated 27-11-2018. The invoice is signed by AD (I&E) DRAP Lahore.
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.

<table>
<tr>
<td>10.</td>
<td>Complete batch manufacturing record of three stability batches.</td>
<td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><th>Batch no.</th><th>Batch Size</th><th>Mfg. Started</th></tr>
<tr><td>19PD-3010-05-T</td><td>2500</td><td>11-2019</td></tr>
<tr><td>19PD-3011-06-T</td><td>2500</td><td>11-2019</td></tr>
<tr><td>19PD-3012-07-T</td><td>2500</td><td>11-2019</td></tr>
</table>
</td>
</tr>
<tr>
<td>11.</td>
<td>Record of comparative dissolution data (where applicable)</td>
<td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Segluromet” The details are as follows:
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of PharmEvo</th></tr>
<tr><td>Brand Name</td><td>Segluromet Tablet 2.5mg/1000 mg</td><td>Erlin-M Tablet 7.5/500mg</td></tr>
<tr><td>Batch No.</td><td>T042906</td><td>19PD-3041-02-T</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
1. pH 1.2 HCl buffer
2. pH 4.5 Acetate buffer
3. pH 6.8 Phosphate buffer
Firm submit letter and clarify that our products Ertugliflozin L-pyroglutamic acid eq to Ertugliflozin + Metformin HCl Tablets 2.5mg + 500mg, 2.5mg + 1000mg, 7.5mg + 500mg & 7.5mg + 1000mg are dose proportional in accordance with EMA Guidelines on the Investigation of Bioequivalence (extract attached) which states that:
- The pharmaceutical products are manufactured by the same manufacturing process.
- The Qualitative composition of the different strengths is the same.
- The composition of strengths are Quantitatively proportional i.e., amount of all the excipients in the
tablet range is similar to each other with respect to tablet weight except filler for which the active substance is adjusted.
In view of the above, we have benchmarked Segluromet Tablet 2.5mg + 1000mg as reference product for all the strengths.
</td>
</tr>
</table>

<table>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>The firm has submitted photocopy of Batch Manufacturing Record of three stability batches such as.

<table><tr><th colspan="3">Ertugliflozin/Metformin</th></tr><tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr><tr><td>19PD-3010-05-T</td><td>30-10-2019</td><td>2500 Tablets</td></tr><tr><td>19PD-3011-06-T</td><td>30-10-2019</td><td>2500 Tablets</td></tr><tr><td>19PD-3012-07-T</td><td>30-10-2019</td><td>2500 Tablets</td></tr></table></td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Yes</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Yes</td></tr>
</table>

REMARKS OF EVALUATOR [VII]

S No	Deficiency	Response
1.	The GMP, quality control department analysis report is from Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China. And on man documents including commercial invoice name is mentioned as Shanghai Pansopharma technology Co., Ltd. Jiangsu China. Provide the relationship.	The Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China is the manufacturer which might be confirmed by the submitted GMP whereas shanghai pansopharm technology co Ltd is an exporter of ertigluphlozin. Declaration letter is provided.
2.	Reference of previous approval of applications with stability study data of the firm is needed	Provided
3.	Certificate of analysis of API from both drug substance and drug product manufacturer	Certificate of analysis of API from both drug substance and drug product manufacturer were provided
4.	Record of comparative dissolution data is needed	Firm submit letter and clarify that our products Ertugliflozin L-pyroglutamic acid eq to Ertugliflozin + Metformin HCl Tablets 2.5mg + 500mg, 2.5mg + 1000mg, 7.5mg + 500mg & 7.5mg + 1000mg are dose proportional in accordance with EMA Guidelines on the Investigation of Bioequivalence (extract attached) which states that: - The pharmaceutical products are manufactured by the same manufacturing process. - The Qualitative composition of the different strengths is the same. - The composition of strengths is Quantitatively proportional i.e., amount of all the excipients in the tablet range is similar to each other with respect to tablet

		weight except filler for which the active substance is adjusted.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of CDP and pharmaceutical equivalence studies, performed against the innovator's product.**

13.	Name, address of Applicant / Marketing Authorization Holder	"M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Name, address of Manufacturing site.	"M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12620 dated 24 May 2022
	Details of fee submitted	PKR 30,000/-: dated 14-04-2022 (10414464710)
	The proposed proprietary name / brand name	Budetrol 400 mcg/12 Mcg DPI capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Budesonide.....400mcg per unit Formoterol fumarate dihydrate.....12mcg
	Pharmaceutical form of applied drug	Transparent Cap & Transparent body of HPMC Capsule
	Pharmacotherapeutic Group of (API)	Corticosteroid/Selective β2 Adrenoceptor (i.e. Short acting and Long acting).
	Reference to Finished product specifications	As per Innovator Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's and as per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYMBICORT TUBOHALER 400/12mcg INHALATION POWDER" by AstraZeneca UK Limited (MHRA approved)
	For generic drugs (me-too status)	Formiget 400mcg + 12mcg DPI capsule of M/s Getz Pharma (Reg # 098723)
	GMP status of the Finished product manufacturer	New additional section of Oral Liquid Syrup approved on: 12-11-2021
	Name and address of API manufacturer.	**Budesonide:** M/s Vamsi Labs LTD, A-14/15, MIDC area, Chincholi Solapur-413255 Maharashtra, INDIA

		Formoterol fumarate dihydrate: M/s Vamsi Labs LTD, A-14/15, MIDC area, Chincholi Solapur-413255 Maharashtra, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Budesonide:** Batches: (BDS/R&D/001/12, BDS/R&D/002/12, BDS/R&D/003/12) **Formoterol Fumarate:** Batches: (FF-006/07, FF-007/07, FF-008/07)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Symbicort Turbuhaler 400mcg/12mcg DPI Capsule by Astrazeneca UK Limited by performing quality tests (Identification, Assay, APSD, DDU of dosage form). CDP is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity, LOD, LOQ.

STABILITY STUDY DATA	
Manufacturer of API	Budesonide: M/s Vamsi Labs Ltd., A-14/15, MIDC area, Chincholi, Solapur-413255, Maharashtra, India Formoterol fumarate dihydrate: M/s Vamsi Labs Ltd., A-14/15, MIDC area, Chincholi, Solapur-413255, Maharashtra, India
API Lot No.	ZIBU21-029
Description of Pack (Container closure system)	DPI capsule
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21-PD-3624-03-T	21-PD-3625-04-T	21-PD-3626-05-T
Batch Size	4000 Capsule	4000 Capsule	4000 Capsule
Manufacturing Date	Mar-2021	Mar-2021	Mar-2021
Date of Initiation	05-2021	05-2021	05-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate (#NEW-WHO GMP/CERT/PD/103627/2021/11/37422) for M/s M/s Vamsi Labs Ltd., A-14/15, MIDC area, Chincholi, Solapur-413255, Maharashtra, India issued by Food and Drugs Administration (Maharashtra State), India. It is valid till 04 Oct 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Budesonide: Firm has submitted copy of invoice specifying purchase of 20 g of Budesonide (micronised) attested by AD Karachi dated 03-12-2020. Formoterol Fumarate Dihydrate: Firm has submitted copy of invoice specifying purchase of 10 g of Formoterol Fumarate Dihydrate (micronized) attested by AD Karachi dated 07-01-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit Trail submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:
Details of DPI device:
Model no.: BDD07
Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China
Shelf life: 3 years

S #	Section	Query	Reply
1.	3.2.S.4	Control of drug substance	Submitted
2.	(2.3.S.4.3)	Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer	Summarized tabulated results of verification studies including specificity, accuracy and Repeatability (method precision) is submitted
3.	(3.2.S.4.4)	Provide results of analysis of relevant	Results of analysis of relevant batch(es) of Drug Substance

		batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture	performed by Drug Product Manufacturer along with COA's has been submitted.
4.	" (3.2.S.4)	Submitted specifications does not include test for "Particle size distribution since, reference product literature states that "The particle size distribution is crucial to achieving the required delivered dose and lung deposition characteristics	Submitted specifications include test for "Particle size distribution" (copy of relevant section is provided
5.	(3.2.P.2.2.1).	The reference products referred by you, is an inspiratory flow-driven, multidose powder inhaler containing metered doses, wherein inhaler is made of different plastic materials, while the applied formulation is primarily pre-dispensed in unit dose hard capsules. Justification shall be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule & method of administration	Innovator has directly filled Active Pharmaceutical Ingredients and Excipients in a blister foil, however we have used capsule as a container of Dry Powder Inhaler products therefore practically it is not possible to fill such a minute quantity of Lactose (as in case of innovator) during encapsulation. Furthermore, Pharmaceutical Equivalence has also been done which exhibit similar result as that of innovator product. Pharmaceutical equivalence including Deliver Dose Uniformity by DUSA & Aerodynamic Particle Size Distribution by Cascade Impaction has been conducted with the Innovator Product (Symbicort Turbo haler); results are similar as that of innovator product. As far as the primary container closure system is concern, we would like bring it in your kind information that HPMC Capsule Shell which is inert in nature; has been used in our formulation. Hence there is no impact of capsule shells on the formulation.
6.	(3.2.P.3.3).	Clarification shall be submitted regarding how the required micronized particle size of the formulation blend has been achieved using Multi-dimensional mixer	Multi-dimensional mixer is used to blend formulation rather than reducing or controlling the particle. Since all the excipients and API used in the formulation is micronized particle size i.e. DPI grade (COA's enclosed for your reference) therefore there is no need of further reduction in particle size at our end.

7.		Evidence of availability of requisite manufacturing & analytical equipment as decided by Registration Board in its 290th meeting at the time of manufacturing of trial batches, shall be submitted.	Evidence of manufacturing & analytical equipment's We have submitted the Installation Qualification and Operational Qualification Protocol and report as the evidence of manufacturing & analytical equipment's.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm will use DPI device Model no.: BDD07 of Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China**

14.	Name, address of Applicant / Marketing Authorization Holder	"M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Name, address of Manufacturing site.	"M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12814 dated 25 May 2022
	Details of fee submitted	PKR 30,000/-: dated 14-04-2022 (10414464710)
	The proposed proprietary name / brand name	Budetrol 200 mcg/6 mcg DPI capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains: Budesonide ..... 200mcg Formoterol Fumarate …... 6mcg Each delivered dose (the dose that leaves the mouthpiece) contains Budesonide 160mcg/inhalation and Formoterol fumarate dihydrate 4.5mcg/inhalation
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Corticosteroid/Selective β2 Adrenoceptor (i.e. Short acting and Long acting).
	Reference to Finished product specifications	As per Innovator Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's and as per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYMBICORT TUBOHALER 200/6mcg INHALATION POWDER" by AstraZeneca UK Limited (MHRA approved)
	For generic drugs (me-too status)	Formiget 200mcg + 6 mcg DPI capsule of M/s Getz Pharma

	GMP status of the Finished product manufacturer	New additional section of Oral Liquid Syrup approved on: 12-11-2021
	Name and address of API manufacturer.	**Budesonide:** M/s Vamsi Labs LTD, A-14/15, MIDC area, Chincholi Solapur-413255 Maharashtra, INDIA **Formoterol fumarate dihydrate:** M/s Vamsi Labs LTD, A-14/15, MIDC area, Chincholi Solapur-413255 Maharashtra, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Budesonide:** Batches: (BDS/R&D/001/12, BDS/R&D/002/12, BDS/R&D/003/12) **Formoterol Fumarate:** Batches: (FF-006/07, FF-007/07, FF-008/07)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Symbicort Turbuhaler 200mcg/6mcg DPI Capsule by Astrazeneca UK Limited by performing quality tests (Identification, Assay, APSD, DDU of dosage form). CDP is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Budesonide: M/s Vamsi Labs Ltd., A-14/15, MIDC area, Chincholi, Solapur-413255, Maharashtra, India Formoterol fumarate dihydrate: M/s Vamsi Labs Ltd., A-14/15, MIDC area, Chincholi, Solapur-413255, Maharashtra, India		
API Lot No.	Budesonide: BDS-0260920 Formoterol Fumarate: FF-0071119		
Description of Pack (Container closure system)	DPI capsule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-3632-01	21PD-3633-02-T	21PD-3634-03-T
Batch Size	4000 Capsule	4000 Capsule	4000 Capsule
Manufacturing Date	April-2021	April-2021	April-2021
Date of Initiation	06-2021	06-2021	06-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/PD/103627/2021/11/37422 issued by Food & Drug Administration, Mumbai, Maharashtra state, India valid till 04/10/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.10105/20,DRAP/K dated 07/1/2020 is submitted wherein the permission to import different APIs including Budesonide propionate & Formoterol Fumarate for the purpose of test/analysis and stability studies is granted. **Budesonide:** • Commercial invoice attested by DRAP-AD dated 03-12-2020. **Formoterol Fumarate:** • Commercial invoice attested by DRAP-AD dated 02-3-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit Trail submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Details of DPI device:
Model no.: BDD07
Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China
Shelf life: 3 years

S #	Section	Query	Reply
1.	3.2.S.4	Control of drug substance	Submitted
2.	(2.3.S.4.3)	Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer	Summarized tabulated results of verification studies including specificity, accuracy and Repeatability (method precision) is submitted
3.	(3.2.S.4.4)	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture	Results of analysis of relevant batch(es) of Drug Substance performed by Drug Product Manufacturer along with COA's has been submitted.
4.	" (3.2.S.4)	Submitted specifications does not include test for "Particle size distribution since, reference product literature states that "The particle size distribution is crucial to achieving the required delivered dose and lung deposition characteristics	Submitted specifications include test for "Particle size distribution" (copy of relevant section is provided
5.	(3.2.P.2.2.1).	The reference products referred by you, is an inspiratory flow-driven, multidose powder inhaler containing metered doses, wherein inhaler is made of different plastic materials, while the applied formulation is primarily pre-dispensed in unit dose hard capsules. Justification shall be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule & method of administration	Innovator has directly filled Active Pharmaceutical Ingredients and Excipients in a blister foil, however we have used capsule as a container of Dry Powder Inhaler products therefore practically it is not possible to fill such a minute quantity of Lactose (as in case of innovator) during encapsulation. Furthermore, Pharmaceutical Equivalence has also been done which exhibit similar result as that of innovator product. Pharmaceutical equivalence including Deliver Dose Uniformity by DUSA & Aerodynamic Particle Size Distribution by Cascade Impaction has been conducted with the Innovator Product (Symbicort Turbo haler); results are similar as that of innovator product. As far as the primary

			container closure system is concern, we would like bring it in your kind information that HPMC Capsule Shell which is inert in nature; has been used in our formulation. Hence there is no impact of capsule shells on the formulation.
6.	(3.2.P.3.3).	Clarification shall be submitted regarding how the required micronized particle size of the formulation blend has been achieved using Multi-dimensional mixer	Multi-dimensional mixer is used to blend formulation rather than reducing or controlling the particle. Since all the excipients and API used in the formulation is micronized particle size i.e. DPI grade (COA's enclosed for your reference) therefore there is no need of further reduction in particle size at our end.
7.		Evidence of availability of requisite manufacturing & analytical equipment as decided by Registration Board in its 290th meeting at the time of manufacturing of trial batches, shall be submitted.	Evidence of manufacturing & analytical equipment's We have submitted the Installation Qualification and Operational Qualification Protocol and report as the evidence of manufacturing & analytical equipment's.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm will use DPI device Model no.: BDD07 of Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China**

15.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12813 dated 25/May/2022
	Details of fee submitted	PKR 30,000/-: dated 13/10/2021
	The proposed proprietary name / brand name	TIOBRE 18mcg DPI CAPSULE
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains:

		22.5mcg of Tiotropium Bromide Monohydrate equivalent to Tiotropium……18mcg (The delivered dose – the dose that leaves the mouth piece is 10.4 mcg Tiotropium)
	Pharmaceutical form of applied drug	Pink Cap & Transparent body of HPMC Capsule
	Pharmacotherapeutic Group of (API)	Tiotropium is used to treat lung diseases such as asthma and COPD (bronchitis, emphysema).
	Reference to Finished product specifications	As per Innovator Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's and as per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SPIRIVA by M/s BOEHRINGER INGELHEIM USFDA Approved.
	For generic drugs (me-too status)	Aprexo 18mcg DPI Capsule by M/s High-Q, Reg. No. 058490
	GMP status of the Finished product manufacturer	New section granted on 29/04/2022 Dry Powder Inhaler Capsule (General) section approved.
	Name and address of API manufacturer.	M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MDR-VI/001/11, MDR-VI/002/11, MDR-VI/003/11)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Spiriva 18mcg Capsule by BOEHRINGER INGELHEIM by performing

		quality tests (Identification, Assay, APSD, DDU of dosage form). CDP is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity, LOD, LOQ.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA		
API Lot No.	TBM-0161019		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-3531-05-T	21PD-3530-04-T	21PD-3532-06-T
Batch Size	4000 Capsule	4000 Capsule	4000 Capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	3-03-2021	3-03-2021	3-03-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/PD/103627/2021/11/37422 issued by Food & Drug Administration, Mumbai, Maharashtra state, India valid till 04/10/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.10105/20,DRAP/K dated 07/1/2020 is submitted wherein the permission to import different APIs including Tiotropium Bromide for the purpose of test/analysis and stability studies is granted. • Commercial invoice attested by DRAP-AD dated 02-3-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Details of DPI device:
Model no.: BDD07
Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China

Shelf life: 3 years

S #	Section	Query	Reply
1.	3.2.S.4	Control of drug substance	Submitted
2.	(2.3.S.4.3)	Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer	Summarized tabulated results of verification studies including specificity, accuracy and Repeatability (method precision) is submitted
3.	(3.2.S.4.4)	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture	Results of analysis of relevant batch(es) of Drug Substance performed by Drug Product Manufacturer along with COA's has been submitted.
4.	" (3.2.S.4)	Submitted specifications does not include test for "Particle size distribution since, reference product literature states that "The particle size distribution is crucial to achieving the required delivered dose and lung deposition characteristics	Submitted specifications include test for "Particle size distribution" (copy of relevant section is provided
5.	(3.2.P.2.2.1).	Justification shall be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule & method of administration	Our developed product Tiobre 18mcg DPI Capsule is same as that Reference product i.e. Spiriva Handihaler consists of pre-dispensed unit dose hard capsules.
6.	(3.2.P.3.3).	Clarification shall be submitted regarding how the required micronized particle size of the formulation blend has been achieved using Multi-dimensional mixer	Multi-dimensional mixer is used to blend formulation rather than reducing or controlling the particle. Since all the excipients and API used in the formulation is micronized particle size i.e. DPI grade (COA's enclosed for your reference) therefore there is no need of further reduction in particle size at our end.
7.		Evidence of availability of requisite manufacturing & analytical equipment as decided by Registration Board in its 290th meeting at the time of manufacturing of trial batches, shall be submitted.	Evidence of manufacturing & analytical equipment's We have submitted the Installation Qualification and Operational Qualification Protocol and report as the evidence of manufacturing & analytical equipment's.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm will use DPI device Model no.: BDD07 of Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China**

16.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17862 dated 20/06/2022
	Details of fee submitted	PKR 30,000/-: (450903543966) dated 10/06/2022
	The proposed proprietary name / brand name	Ezhale 100mcg+50mcg DPI Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains: Fluticasone Propionate ..... 100mcg Salmeterol Xinafoate 50mcg
	Pharmaceutical form of applied drug	Transparent Cap & Transparent body of HPMC Capsule
	Pharmacotherapeutic Group of (API)	Steroids/Long-acting beta-agonists (LABAs).
	Reference to Finished product specifications	USP
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's and as per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Seretide Accuhaler 50 microgram/100 microgram by M/s GSK UK Limited., MHRA Approved.
	For generic drugs (me-too status)	Salmicort 100mcg+50mcg DPI Capsule by M/s Macter Int. Ltd., Reg. No. 095137
	GMP status of the Finished product manufacturer	New license granted on 29/04/2022 Dry Powder Inhaler Capsule (General) section approved.
	Name and address of API manufacturer.	<u>Fluticasone:</u> M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA. <u>Salmeterol:</u> M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Fluticasone Propionate & Salmeterol Xinafoate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Fluticasone Propionate:** Batches: (FTP-0020218(M), FTP-0030218(M), FTP-0040318(M)) **Salmeterol Xinafoate:** Batches: (SX-0020515, SX-0030515, SX-0040515)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Seretide Accuhaler/Diskus 100/50mcg DPI by GSK group of companies by performing quality tests (Identification, Assay, APSD, DDU of dosage form). CDP is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA
API Lot No.	Fluticasone Propionate: FTP-0150819 Salmeterol Xinafoate: SX-0091119
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-3974-02-T	21PD-3975-03-T	21PD-3976-04-T
Batch Size	4000 capsules	4000 capsules	4000 capsules
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	01-11-2021	01-11-2021	01-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/PD/103627/2021/11/37422 issued by Food & Drug Administration, Mumbai, Maharashtra state, India valid till 04/10/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.0105/20,DRAP/K dated 07/1/2020 is submitted wherein the permission to import different APIs including Fluticasone & Salmeterol for the purpose of test/analysis and stability studies is granted. **Fluticasone Propionate:** • Commercial invoice attested by DRAP-AD dated 02-3-2020. **Salmeterol Xinafoate:** • Commercial invoice attested by DRAP-AD dated 02-3-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

The applied formulation is approved in USFDA is supplied as a disposable purple plastic inhaler containing a foil blister strip with 60 blisters. The inhaler is packaged in a plastic-coated, moisture-protective foil
Firm provides the details of DPI device purchased by shangai Huarui aerosol co. Ltd Shangai china.

Details of DPI device:
Model no.: BDD07
Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China
Shelf life: 3 years

S #	Query	Reponses
1.	Clarification regarding intended manufacturing area, since applied formulation contains Fluticasone, which is a steroid	We have established a segregated facility for the manufacturing of Dry Powder Inhalers (DPI) Capsules. Layout of the said facility has been approved and section approval has also been granted by DRAP on 29th

		April, 2022 (copy enclosed for your ready reference). We would like to bring it in your kind information that below are the measures will be taken in order to control cross-contamination during the manufacturing of subject products: 1. Dedicated change parts are available for the encapsulation of that will ensure and minimize the risk cross contamination during filling process. 2. Dedicated change parts along with auto feeder is installed and available for the blistering of that will further ensure the control of cross contamination during blistering and primary packaging process. 3. Separate gowning procedure will be followed. 4. New HEPA filter will be employed. 5. Specialized dedicated dispensing booth. 6. PRE/POST cleaning validation studies on approved protocol for steroidal formulations has been done so as to make sure the prevention of cross contamination. We also would like to bring to your kind attention that DRAP has already approved the manufacturing of all DPI's (Steroidal) in General DPI section in its 294th & 297th meeting minutes (copy of relevant pages are enclosed for your ready reference).
2.	Evidence of availability of requisite manufacturing & analytical equipment's as decided by Registration also Evidence of equipment's for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia	We have submitted the Installation Qualification and Operational Qualification Protocol and Report as the evidence of manufacturing & analytical equipment's as per Pharmacopoeia.
3.	In reference products referred by you, formulation is pre-dispensed in a foil blistered strips, whereas applied formulation is primarily pre-dispensed in hard capsules. Justification shall be submitted for change in primary container closure system with respect to compatibility of applied formulation with the hard gelatine capsules.	Pharmaceutical equivalence including Deliver Dose Uniformity by DUSA & Aerodynamic Particle Size Distribution by Cascade Impaction has been conducted with the Innovator Product (Seretide Diskus); results are similar as that of innovator product. 2. As far as the primary container closure system is concern, we would like bring it in your kind information that HPMC Capsule Shell which is inert in nature; has been used in our formulation. Hence

		there is no impact of capsule shells on the formulation. We also would like to bring your kind attention that DRAP has already approved Salmeterol + Fluticasone propionate in HPMC capsules in its 275th DRB meeting for M/s Macter International Ltd., Karachi with the brand name of Salmicort DPI Capsule and in 291st DRB meeting for M/s Getz (Pvt.) Ltd., Karachi with the brand name of Saltra DPI Capsule (extract attached).
4.	Details of reference product batch # import details Mfg. date etc against which pharmaceutical equivalence was established	Pharmaceutical equivalence report enclosed which comprises the detail of reference product i.e. Seretide Diskus, including batch number, manufacturing date, expiry date etc.
5.	Under standardized in vitro test conditions, ADVAIR DISKUS delivers 465mcg of fluticasone propionate and 45mcg of salmeterol base per blister from ADVAIR DISKUS when tested at a flow rate of 60L/min. for 2 seconds while you have not submitted any label claim for delivered dose	Label claim for deliver dose have been submitted with initial registration dossier however we are again submit the copy of relevant section for your reference.
6.	Clarification shall be submitted regarding how the required micronized particle size of the formulation blend has been achieved using Multi-dimensional mixer	Multi-dimensional mixer is used to blend formulation rather than reducing or controlling the particle. Since all the excipients and API used in the formulation is micronized particle size i.e. DPI grade (COA's attached) therefore there is no need of further reduction in particle size at our end.
7.	Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer (2.3.S.4.3)	Summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) is already submitted with initial registration dossier, however we are again submit the copy of relevant section for your reference.
8.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture (3.2.S.4.4)	Results of analysis of relevant batch(es) of Drug Substance performed by Drug Product Manufacturer along with COA's has been submitted with initial registration dossier, however we are again submit the COA's for your reference.
9.	Submitted specifications does not include details of test for "Particle size distribution since reference product literature states that "The particle size distribution is crucial to achieving the required delivered dose and lung deposition characteristics (3.2.S.4)	Submitted specifications include test for "Particle size distribution" (copy of relevant section is enclosed for your ready reference).

10.	Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer (2.3.S.4.3)	Summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) is already submitted with initial registration dossier, however we are again submit the copy of relevant in Annexure-7 for your further proceeding.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm will use DPI device Model no.: BDD07 of Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China**

17.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18005 dated 21/06/2022
	Details of fee submitted	PKR 30,000/-: dated 10/06/2022
	The proposed proprietary name / brand name	Ezhale 250mcg+50mcg DPI Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains: Fluticasone Propionate ..... 250mcg Salmeterol Xinafoate 50mcg
	Pharmaceutical form of applied drug	Transparent Cap & Transparent body of HPMC Capsule
	Pharmacotherapeutic Group of (API)	Steroids/Long-acting beta-agonists (LABAs).
	Reference to Finished product specifications	USP
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's and as per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Seretide Accuhaler 50 microgram/250 microgram by M/s GSK UK Limited., MHRA Approved.
	For generic drugs (me-too status)	Salmicort 250mcg+50mcg DPI Capsule by M/s Macter Int. Ltd., Reg. No. 095138
	GMP status of the Finished product manufacturer	New license granted on 29/04/2022 Dry Powder Inhaler Capsule (General) section approved.

	Name and address of API manufacturer.	M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Fluticasone Propionate & Salmeterol Xinafoate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Fluticasone Propionate:** Batches: (FTP-0020218(M), FTP-0030218(M), FTP-0040318(M)) **Salmeterol Xinafoate:** Batches: (SX-0020515, SX-0030515, SX-0040515)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Seretide Accuhaler/Diskus 250/50mcg DPI by GSK group of companies by performing quality tests (Identification, Assay, APSD, DDU of dosage form). CDP is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA
API Lot No.	Fluticasone Propionate: FTP-0150819 Salmeterol Xinafoate: SX-0091119

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-3971-02-T	21PD-3972-03-T	21PD-3973-04-T
Batch Size	4000 capsules	4000 capsules	4000 capsules
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	01-11-2021	01-11-2021	01-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/PD/103627/2021/11/37422 issued by Food & Drug Administration, Mumbai, Maharashtra state, India valid till 04/10/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.0105/20,DRAP/K dated 07/1/2020 is submitted wherein the permission to import different APIs including Fluticasone & Salmeterol for the purpose of test/analysis and stability studies is granted. **Fluticasone Propionate:** • Commercial invoice attested by DRAP-AD dated 02-3-2020. **Salmeterol Xinafoate:** • Commercial invoice attested by DRAP-AD dated 02-3-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

The applied formulation is approved in USFDA is supplied as a disposable purple plastic inhaler containing a foil blister strip with 60 blisters. The inhaler is packaged in a plastic-coated, moisture-protective foil
Firm provides the details of DPI device purchased by shangai Huarui aerosol co. Ltd Shangai china.
Details of DPI device:
Model no.: BDD07
Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China
Shelf life: 3 years

S #	Query	Reponses
1.	Clarification regarding intended manufacturing area, since applied formulation contains Fluticasone, which is a steroid	We have established a segregated facility for the manufacturing of Dry Powder Inhalers (DPI) Capsules. Layout of the said facility has been approved and section approval has also been granted by DRAP on 29th April, 2022 (copy enclosed for your ready reference). We would like to bring it in your kind information that below are the measures will be taken in order to control cross-contamination during the manufacturing of subject products: 1. Dedicated change parts are available for the encapsulation of that will ensure and minimize the risk cross contamination during filling process. 2. Dedicated change parts along with auto feeder is installed and available for the blistering of that will further ensure the control of cross contamination during blistering and primary packaging process. 3. Separate gowning procedure will be followed. 4. New HEPA filter will be employed. 5. Specialized dedicated dispensing booth. 6. PRE/POST cleaning validation studies on approved protocol for steroidal formulations has been done so as to make sure the prevention of cross contamination. We also would like to bring to your kind attention that DRAP has already approved the manufacturing of all DPI's (Steroidal) in General DPI section in its 294th & 297th meeting minutes (copy of relevant pages are enclosed for your ready reference).
2.	Evidence of availability of requisite manufacturing & analytical equipment's as decided by Registration also Evidence of equipment's for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia	We have submitted the Installation Qualification and Operational Qualification Protocol and Report as the evidence of manufacturing & analytical equipment's as per Pharmacopoeia.
3.	In reference products referred by you, formulation is pre-dispensed in a foil blistered strips, whereas applied formulation is primarily pre-dispensed in hard capsules. Justification shall be submitted for change in primary container closure system with respect to	Pharmaceutical equivalence including Deliver Dose Uniformity by DUSA & Aerodynamic Particle Size Distribution by Cascade Impaction has been conducted with the Innovator Product (Seretide

	compatibility of applied formulation with the hard gelatine capsules.	Diskus); results are similar as that of innovator product. 2. As far as the primary container closure system is concern, we would like bring it in your kind information that HPMC Capsule Shell which is inert in nature; has been used in our formulation. Hence there is no impact of capsule shells on the formulation. We also would like to bring your kind attention that DRAP has already approved Salmeterol + Fluticasone propionate in HPMC capsules in its 275th DRB meeting for M/s Macter International Ltd., Karachi with the brand name of Salmicort DPI Capsule and in 291st DRB meeting for M/s Getz (Pvt.) Ltd., Karachi with the brand name of Saltra DPI Capsule (extract attached).
4.	Details of reference product batch # import details Mfg. date etc against which pharmaceutical equivalence was established	Pharmaceutical equivalence report enclosed which comprises the detail of reference product i.e. Seretide Diskus, including batch number, manufacturing date, expiry date etc.
5.	Under standardized in vitro test conditions, ADVAIR DISKUS delivers 465mcg of fluticasone propionate and 45mcg of salmeterol base per blister from ADVAIR DISKUS when tested at a flow rate of 60L/min. for 2 seconds while you have not submitted any label claim for delivered dose	Label claim for deliver dose have been submitted with initial registration dossier however we are again submit the copy of relevant section for your reference.
6.	Clarification shall be submitted regarding how the required micronized particle size of the formulation blend has been achieved using Multi-dimensional mixer	Multi-dimensional mixer is used to blend formulation rather than reducing or controlling the particle. Since all the excipients and API used in the formulation is micronized particle size i.e. DPI grade (COA's attached) therefore there is no need of further reduction in particle size at our end.
7.	Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer (2.3.S.4.3)	Summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) is already submitted with initial registration dossier, however we are again submit the copy of relevant section for your reference.
8.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture (3.2.S.4.4)	Results of analysis of relevant batch(es) of Drug Substance performed by Drug Product Manufacturer along with COA's has been submitted with initial registration dossier, however we are

		again submit the COA's for your reference.
9.	Submitted specifications does not include details of test for "Particle size distribution since reference product literature states that "The particle size distribution is crucial to achieving the required delivered dose and lung deposition characteristics (3.2.S.4)	Submitted specifications include test for "Particle size distribution" (copy of relevant section is enclosed for your ready reference).

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm will use DPI device Model no.: BDD07 of Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China**

18.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20728 dated 22/07/2022
	Details of fee submitted	PKR 30,000/-: dated 10/06/2022
	The proposed proprietary name / brand name	Ezhale 500mcg+50mcg DPI Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains: Fluticasone Propionate ..... 500mcg Salmeterol Xinafoate 50mcg
	Pharmaceutical form of applied drug	Transparent Cap & Transparent body of HPMC Capsule
	Pharmacotherapeutic Group of (API)	Steroids/Long-acting beta-agonists (LABAs).
	Reference to Finished product specifications	USP
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's and as per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Seretide Accuhaler 50 microgram/500 microgram by M/s GSK UK Limited., MHRA Approved.
	For generic drugs (me-too status)	Oxytide-F 500+50mcg Capsule by M/s Werrick Pharmaceutical, Reg. No. 095348
	GMP status of the Finished product manufacturer	New license granted on 29/04/2022 Dry Powder Inhaler Capsule (General) section approved.

	Name and address of API manufacturer.	M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Fluticasone Propionate & Salmeterol Xinafoate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Fluticasone Propionate:** Batches: (FTP-0020218(M), FTP-0030218(M), FTP-0040318(M)) **Salmeterol Xinafoate:** Batches: (SX-0020515, SX-0030515, SX-0040515)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Seretide Accuhaler/Diskus 500/50mcg DPI by GSK group of companies by performing quality tests (Identification, Assay, APSD, DDU of dosage form). CDP is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vamsi Labs. Ltd. A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra. INDIA
API Lot No.	Fluticasone Propionate: FTP-0150819 Salmeterol Xinafoate: SX-0091119

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-3979-02-T	21PD-3980-03-T	21PD-3981-04-T
Batch Size	4000 capsules	4000 capsules	4000 capsules
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	01-11-2021	01-11-2021	01-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/PD/103627/2021/11/37422 issued by Food & Drug Administration, Mumbai, Maharashtra state, India valid till 04/10/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.0105/20,DRAP/K dated 07/1/2020 is submitted wherein the permission to import different APIs including Fluticasone & Salmeterol for the purpose of test/analysis and stability studies is granted. **Fluticasone Propionate:** • Commercial invoice attested by DRAP-AD dated 02-3-2020. **Salmeterol Xinafoate:** • Commercial invoice attested by DRAP-AD dated 02-3-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

The applied formulation is approved in USFDA is supplied as a disposable purple plastic inhaler containing a foil blister strip with 60 blisters. The inhaler is packaged in a plastic-coated, moisture-protective foil
Firm provides the details of DPI device purchased by shangai Huarui aerosol co. Ltd Shangai china.

S #	Query	Reponses
1.	Clarification regarding intended manufacturing area, since applied formulation contains Fluticasone, which is a steroid	We have established a segregated facility for the manufacturing of Dry Powder Inhalers (DPI) Capsules. Layout of the said facility has been approved and section approval has also been granted by DRAP on 29th

		April, 2022 (copy enclosed for your ready reference). We would like to bring it in your kind information that below are the measures will be taken in order to control cross-contamination during the manufacturing of subject products: 1. Dedicated change parts are available for the encapsulation of that will ensure and minimize the risk cross contamination during filling process. 2. Dedicated change parts along with auto feeder is installed and available for the blistering of that will further ensure the control of cross contamination during blistering and primary packaging process. 3. Separate gowning procedure will be followed. 4. New HEPA filter will be employed. 5. Specialized dedicated dispensing booth. 6. PRE/POST cleaning validation studies on approved protocol for steroidal formulations has been done so as to make sure the prevention of cross contamination. We also would like to bring to your kind attention that DRAP has already approved the manufacturing of all DPI's (Steroidal) in General DPI section in its 294th & 297th meeting minutes (copy of relevant pages are enclosed for your ready reference).
2.	Evidence of availability of requisite manufacturing & analytical equipment's as decided by Registration also Evidence of equipment's for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia	We have submitted the Installation Qualification and Operational Qualification Protocol and Report as the evidence of manufacturing & analytical equipment's as per Pharmacopoeia.
3.	In reference products referred by you, formulation is pre-dispensed in a foil blistered strips, whereas applied formulation is primarily pre-dispensed in hard capsules. Justification shall be submitted for change in primary container closure system with respect to compatibility of applied formulation with the hard gelatine capsules.	Pharmaceutical equivalence including Deliver Dose Uniformity by DUSA & Aerodynamic Particle Size Distribution by Cascade Impaction has been conducted with the Innovator Product (Seretide Diskus); results are similar as that of innovator product. 2. As far as the primary container closure system is concern, we would like bring it in your kind information that HPMC Capsule Shell which is inert in nature; has been used in our formulation. Hence

		there is no impact of capsule shells on the formulation. We also would like to bring your kind attention that DRAP has already approved Salmeterol + Fluticasone propionate in HPMC capsules in its 275th DRB meeting for M/s Macter International Ltd., Karachi with the brand name of Salmicort DPI Capsule and in 291st DRB meeting for M/s Getz (Pvt.) Ltd., Karachi with the brand name of Saltra DPI Capsule (extract attached).
4.	Details of reference product batch # import details Mfg. date etc against which pharmaceutical equivalence was established	Pharmaceutical equivalence report enclosed which comprises the detail of reference product i.e. Seretide Diskus, including batch number, manufacturing date, expiry date etc.
5.	Under standardized in vitro test conditions, ADVAIR DISKUS delivers 465mcg of fluticasone propionate and 45mcg of salmeterol base per blister from ADVAIR DISKUS when tested at a flow rate of 60L/min. for 2 seconds while you have not submitted any label claim for delivered dose	Label claim for deliver dose have been submitted with initial registration dossier however we are again submit the copy of relevant section for your reference.
6.	Clarification shall be submitted regarding how the required micronized particle size of the formulation blend has been achieved using Multi-dimensional mixer	Multi-dimensional mixer is used to blend formulation rather than reducing or controlling the particle. Since all the excipients and API used in the formulation is micronized particle size i.e. DPI grade (COA's attached) therefore there is no need of further reduction in particle size at our end.
7.	Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer (2.3.S.4.3)	Summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) is already submitted with initial registration dossier, however we are again submit the copy of relevant section for your reference.
8.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture (3.2.S.4.4)	Results of analysis of relevant batch(es) of Drug Substance performed by Drug Product Manufacturer along with COA's has been submitted with initial registration dossier, however we are again submit the COA's for your reference.
9.	Submitted specifications does not include details of test for "Particle size distribution since reference product literature states that "The particle size distribution is crucial to achieving the required delivered dose and lung deposition characteristics (3.2.S.4)	Submitted specifications include test for "Particle size distribution" (copy of relevant section is enclosed for your ready reference).

Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **The firm will use DPI device Model no.: BDD07 of Manufacturer: M/s ShangHai HuaRui Aerosol Co., Ltd. No.222, Yuanchun Road, Pudong New Area, Shanghai, China**

Case No. 02 Registration applications of drugs for which stability study data is submitted Registration applications for Form 5F

a) Form 5F Import (Human)

19.	**Name, address of Applicant / Importer**	**M/s Al-Habib Pharmaceuticals, Plot #81, block B, SMCHS, Karachi.**
	Details of Drug Sale License of importer	DSL No.: 0230 Address: Al-Habib Pharmaceuticals, 81-B, block B, SMCHS, Karachi. Godown: 1. Plot No. 393/7 & 393/8 Sector 7-A KIA Karachi Validity: 18/05/2024 Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Laboratories IMA S.A.I.C, Palpa 2862, Ciudad Autonoma de Buenos Aires, Argentina.
	Name, address of manufacturer(s)	M/s Laboratorios IMA S.A.I.C, Palpa 2862, Ciudad Autonoma de Buenos Aires, Argentina.
	Name of exporting country	Argentina
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized CoPP (certificate No. 191106) valid till 30-10-2021 issued by National Institute of Drugs, Argentina. The applied product is available for free sale in exporting country. The facilities and operations conform to WHO-GMP.
	Details of letter of authorization / sole agency agreement	Notarized copy of sole agency agreement is submitted whereby M/s Laboratorios IMA S.A.I.C, authorizes M/s Al-Habib Pharmaceuticals to Import and commercialize different products including Gemcitabine injection.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging

		☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.22751: 20-08-2021
	Details of fee submitted	PKR 100,000 Dated: 29-03-2021 Differential fee : PKR 50,000 Dated : 05-07-2021
	The proposed proprietary name / brand name	**GEMSTAR 200 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Gemcitabine HCl ……. 200 mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Anti-Cancer (Nucleoside) (L01BC05)
	Reference to Finished product specifications	USP
	Proposed Pack size	1 Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Gemzar® 200 mg injection (**USFDA** Approved) by Eli Lilly
	For generic drugs (me-too status)	Gemzar® 200 mg injection by Eli Lilly Pakistan (PvtP Ltd
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Hetero Labs Limited Survey.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ± 2°C. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product Gemzar® 200mg injection by Eli Lilly
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I, amber glass vial 50 ml Bromobutyl elastomeric stopper. Aluminum capsule with flip off closure.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches 24 months real time stability data at 30°C ± 2°C / 75% ± 5%RH of 03 batches 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches

Evaluation by PEC:

S No	Section #.	Deficiencies	Response
1.	**1.33**	Importer shall provide valid Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority in the country of origin and name of exporting country.	Original legalized CoPP (certificate No. 191106) valid till 30-10-2021 issued by National Institute of Drugs, Argentina. The applied product is available for free sale in exporting country. The facilities and operations conform to WHO-GMP. Firm submitted that "This get expired during its period in R& I that's why as per rule it will be considered as valid"
2.	**1.33**	The GMp of shanghai acebright pharma co ltd. China is provided as API manufacture but at some place Hetero Labs Limited Survey.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA is mentioned as API manufacturer clarification is needed in this regard.	Hetero Labs Limited Survey.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA is API manufacturer, its GMP is provided
3.	**1.33**	The GMP certificate of Laboratories IMA SAIC Argentina issued by National administration of drug, food and medical devices (ANMAT)is valid till 2 April 2021. Provides Valid GMP	The GMP certificate of Laboratories IMA SAIC Argentina issued by National administration of drug, food and medical devices (ANMAT) valid till 3 April 2022 is provided
4.	***2.3.S***	On API stability both IMA lab and Hetro lab is mentioned justify	No justification is given

Decision: Deferred for following:

- **Clarification regarding the site wherein stability studies of drug substance have been performed, since in submitted stability sheets both IMA lab and Hetro lab is mentioned.**

Case no. 02 Registration applications of drugs for which stability study data is submitted Registration applications for Form 5F

a) Form 5F Deferred (Human)

20.	Name, address of Applicant / Marketing Authorization Holder	M/s Nawan Laboratories Ltd. 136, sector 15, KIA, Korangi Karachi from M/s Bio-Labs (Pvt) Ltd
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8005 dated 11-03-2021
	Details of fee submitted	PKR 50,000/- (#2009144) dated 17-02-2021
	The proposed proprietary name / brand name	Nevitix Injection 500mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Mecobalamin ……. 500mcg
	Pharmaceutical form of applied drug	Almost red colour solution filled in amber glass ampoule.
	Pharmacotherapeutic Group of (API)	Antianemia
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1ml x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Methycobal Injection PMDA approved
	For generic drugs (me-too status)	Amcobal Injection 500mcg/ml by Amson Vaccine & Pharma 069899
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conduct 23-4-2019, valid upto 22-4-2022.
	Name and address of API manufacturer.	M/s. Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. (assay by HPLC with PDA detector, limit 98to 101%), residual solvent by GC
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 ^{O} ± 2 ^{O} C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2 ^{O} C / 65% ± 5% RH for 48 months (batch no. 7805016001, 7805016002 & 7805016003).
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Methycobal 500 mg injection by Hilton Pharma
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India
API Lot No.	MCB2010061
Description of Pack	Glass vial

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	A-431	A-443	A-456
Batch Size	37,000 Ampoules	10,000 Ampoules	10,800 ampoules
Manufacturing Date	04-2018	05-2018	06-2018
Date of Initiation	29-8-2018	2-7-2018	10-09-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate # 20031928 of M/s. Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India valid upto 16-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted attested copy of invoice (invoice # HHM/2021/00256) attested by AD DRAP
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator [VII]:

Sr. No.	Section #.	Deficiencies	Reply
1.	***3.2.P.2***	How much overage is added in the formulation? Justify the percentage of overage added in the formulation	30% overage is added
2.	***3.2.P.8***	Justify the selection of limit of assay test as "90 – 150 %" while the official limit of vitamin preparations is 120%.	For the case of Vitamin preparations normally and most of the cases followed Compendial limits are 90-130%. In our nivitex inj 500mcg we have added 30% of overage in the batch formula. Unit contains 30% of overage of API, So considering the addition of 30% of overage, assay limits are set as 90-150%.

			We have now revised the specs and make it more stringent after complete stability data and market feedback, so the revised limits are now set as 90-130%.
3.	***3.2.P.8***	Justify how UV method was adopted for the testing of drug product, since the testing method of drug substance manufacturer for assay of mecobalamin was based on HPLC	M/s Bio-labs have the registration of our product Mine injection as per manufacture specification and UV-VIS Spectrophotometer method is DRAP approved method. Since stability data is proved at old batches of 2018 so the applied method is UV-VIS Spectrophotometer which has been updated now. Validation of the applied testing method has been provided in terms of all the parameters as per validation guidelines.
4.	***3.2.P.8***	Justify the effective date on stability data sheet is 01-01-2020 but the stability starts at 29-08-2018	Effective data on stability data sheet is 01-01-2020 because old data has been provided on the new formats. Formats for interpretations of stability results are new and revised with old stability data for presentation.
5.	***3.2.P.8***	Justify the results of assay as all the batches just showed minor decrease in assay results less than which is usually observed in vitamin preparations. Scientific justification / clarification is required in this regard.	Results of assay showed normal decrease in assay results, which is well within the trend as of vitamins preparation. In the stability data provided, assay results decrease gradually e.g. in batch number A-431 assay results decreases from 122…62% to 109-93% (stability sheet for real time analysis provided), in batch number A-433 assay results decreased from 121.21% to 107-23% and in batch number A-456 results decreased from 121.2% to 106-83%.

Decision of 316: Deferred for the following
Justify how UV method was adopted for the testing of drug product, since the testing method of drug substance manufacturer for assay of mecobalamin was based on HPLC
Justification for the results of assay
Justification of the percentage of overage added in the formulation

Remarks of evaluator PEC VII

S. No.	Deficiency in 316th Meeting	Documents Attached
1.	Deferred for: • Justification of applying UV Spectrophotometric method for the assay test of drug product, since the testing method of drug substance manufacturer for assay of mecobalamin was based on HPLC.	Bio-Labs has registration of mecobalamine injection as per manufacturer specifications. Since stability data has been provided of old batches so applied testing method along with method validation was submitted. However, the testing method of the mecobalamine injection has been updated to HPLC. The method validation of the new method is attached herewith. Both the methods (UV-spectrophotometric and HPLC) are validated in all aspects of ICH guidelines.
	• Justification for declining trend of assay results.	As the mecobalamin is light sensitive product and gradually degrades with the time, due to this reason there is declining trend in the analysis of assay. In order to achieve patient compliance and provision of complete dose, overage has been added so that the contents of API remain within claim limit during product shelf life.
	• Justification of the percentage of overage added in the formulation.	As the mecobalamine is light sensitive product and gradually degrades with the time, due to this reason there is declining trend in the analysis of assay. In order to achieve patient compliance and provision of complete dose, overage has been added so that the contents of API remain within claim limit during product shelf life.

Decision: Registration Board noted the fact that the %age overage used in the applied formulation was above the general permissible limits of overage hence the Board deferred the case for submission of new 6 month stability studies data of drug product at accelerated and long term conditions of Zone IVA, with revised formulation excluding overage, drug product specifications and drug product analytical procedure based upon HPLC Assay method.

21.	Name, address of Applicant / Marketing Authorization Holder	**M/s Novamed Pharmaceuticals (Pvt.) Ltd Lahore**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt.) Ltd., 28km Ferozepur Road Lahore
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7175 dated 04/03/2021
	Details of fee submitted	PKR 50,000/-: dated 18/5/2020 (#2004310)
	The proposed proprietary name / brand name	**Invid -3 Injection 300,000IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Cholecalciferol……..…300,000IU
	Pharmaceutical form of applied drug	Clear colorless oily liquid free from foreign particles
	Pharmacotherapeutic Group of (API)	Fat soluble vitamin, Vitamin-D Analogue (IM injection)
	Reference to Finished product specifications	Manufacturer Specs
	Proposed Pack size	1's (1ml), 5's (1ml), 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XARENEL 300,000 IU / ml solution for injection Italy Approved
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	License granted on 08/04/2006 and renewed on 08/04/2021 General liquid section approved and GMP certificate on 06/08/2021
	Name and address of API manufacturer.	Sichuan Province Yuxin Pharmaceutical Co., Ltd. Weicheng Jinhe East Road, Shifang City, Sichuan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions:

		Real time: 5°C ± 3°C / 65% ± 5% RH for 48 months Accelerated: 25°C ± 2°C / 75% ± 5%RH for 6 months Batches: (B-3-01-130601 , B-3-01-130602 , B-3-01-130603)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is **Dibase by Abiogen Pharmaceuticals** by performing quality tests (Identification, Assay, Dissolution,). CDP has not been applicable
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
	Remarks: The excipient use is XARENEL 300,000 IU / ml solution for injection: refined olive oil for injectable use. The overage added is 25% The membrane filtration is done Particulate matter is counted by particulate counter	

STABILITY STUDY DATA			
Manufacturer of API	Sichuan Province Yuxin Pharmaceutical Co., Ltd. Weicheng Jinhe East Road, Shifang City, Sichuan		
API Lot No.	B-1-51-M190105		
Description of Pack (Container closure system)	USP Type-1 Glass ampoule blistered in Alu - PVC and further packed in unit carton (1's ,5's (1ml)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TP-140-T2	TP-140-T3	TP-140-T4
Batch Size	5000 Ampoule	5000 Ampoule	5000 Ampoule
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	25-07-2019	27-07-2019	27-07-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted copy of Last inspection Report conducted on 24/01/2018.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SC20160032 issued by CFDA valid till 17/11/2021.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of AD Attested invoice No F 1919090 vide No.5354/2019/DRAP-AD-CD(I&E) dated 16/04/2019 is submitted wherein the permission to import Vitamin D3 API is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator [VII]:

S. No	Sections	Observations/ Short-comings	Remarks
1.	**1.3.4**	Valid Drug Manufacturing License (DML) of manufacturer/Applicant shall be submitted as submitted DML was not valid.	Copy of valid DML is submitted
2.	**2.3.R.1.1**	Provide copy of Batch manufacturing record (BMR) for all the batches of the drug product for which stability study data is provide in module 3 section 3.2.P.8.3.	Copies of Executed/Trial batches & Commercial batch BMR were attracted in 3.2.R. However, Copies of BMR of all the batches of the drug product for which stability study data are provided in 2.3.R.1.1.
3.	**3.2.P.8**	Stability: on commercial Invoice the quantity mentioned was Vit D3 40MIU but the prepare strength is 300,000IU	As per COA,40MIU is the potency of vitamin D3 i.e 40,000,000 IU/gm , as per label claim of the applied strength the quantity of vitamin d3 with this potency is calculated which is equivalent to vitamin d3 300,000IU (7.5 mg). COA and calculation is attached.
4.	**3.2.P.1**	The composition contains BHA and Crodamol oil but in the reference product Xarenel 300,000IU/ml solution for injection. The excipient use is refined olive oil for injectable use.	Compatibility of crodamol oil and BHA were performed against Vitamin d3 Active, no interference was observed during the compatibility Analysis
5.	**3.2.P.1**	Description and composition of the drug product Details of Overage not provide in the formulation	Overage was reflecting in the amount of API /unit, however composition with overage details is attached.
6.	**3.2.S.7.3**	Justification of the stability of the drug substance at 25˚C±2˚C/ 60%RH±5%RH. In case where the real time stability data of the drug substance is conducted at 25˚C±2˚C/60%RH±5%RH,	Revised Stability Data of new batches is provided

		The firm shall submit the record of data logger for the storage condition throughout the transportation.	
7.	**3.2.S.4.1**	Specification assay limit is mentioned as 97-103% but in USP the limit is from 90-120%.	According to **USP 42 NF 37** Acceptance criteria limit for Cholecalciferol material is 97-103%.Copy of USP monograph is provided for reference.
8.	**3.2.P.1**	In composition no Overage is mentioned in this section.	Overage was reflecting in the amount of API /unit, however composition with overage details is provided.
9.	**2.3.P.3.2**	In 2.3.P.3.2 batch formula it is mentioned that after 6 month of accelerated and real time stability studies product is stable so overage will be omitted during commercial validation batches but in the assay, there is a steady decrease in assay limit. Justification is needed about this statement.	Vitamins generally have tendency to degrade. As vitamin D3 is photolytic, thermally unstable and have oxidative nature but at the same time it is a fat-soluble vitamin and more stable with Crodamol Oil, because of this property product show no significant change in assay as defined in guideline.
10.	**3.2.A and 3.2R**	Appendices and regional information is missing.	Appendices and regional information as per approved checklist of 296th DRB is attached.
11.	**3.2.P.8**	Justify the result of Assay as all the batches just showed minor decrease in assay results less than which is usually observed in vitamin preparations. Scientific Justification/clarification is required in this regard.	Vitamins generally have tendency to degrade. As vitamin D3 is photolytic, thermally unstable and have oxidative nature but at the same time it is a fat-soluble vitamin and more stable with Crodamol Oil, because of this property product show no significant change in assay as defined in guideline.
12.	**3.2.P.2.1.1**	As As per relevant guidelines & structure of Form 5F, Comparative assay Pharmaceutical equivalence has to be performed at the time formulation development, while according to your submitted data, it has been performed after commencing stability studies. Justification shall be submitted.	Owing to the prevailed condition of covid throughout the world We had performed PE after formulation development due to unavailability of the Innovator pack. So, as per the need of hour or to overcome this challenge we deviated from the chronological flow. However, we confirm that this deviation will not be repeated.

Decision of 316:

Deferred for the following

The applied product's monograph is present in BP but the specification and methods applied are not according to BP monograph.

Remarks of evaluator VII

In BP monograph method given for assay analysis is by UV spectroscopy while invid-3 was tested by more stringent HPLC method. As a matter of fact, HPLC method exhibited the advantage of high precision and high recovery and high sensitivity

Decision of 321st meeting: Deferred for comparative analysis of drug product specification proposed by the applicant and those recommended by BP monograph of Vitamin D3 injection.

22.	Name, address of Applicant / Marketing Authorization Holder	M/s Valor Pharmaceuticals, 124/A Industrial Triangle, Kahuta Road Islamabad.

	Name, address of Manufacturing site.	M/s Valor Pharmaceuticals, 124/A Industrial Triangle, Kahuta Road Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23210 dated 30-aug-2021
	Details of fee submitted	PKR 20,000/- + 10,000 dated 11/12/2020
	The proposed proprietary name / brand name	Valofam 250mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Famciclovir ……250mg
	Pharmaceutical form of applied drug	White, Round shaped, bisect oral tablet
	Pharmacotherapeutic Group of (API)	Antivirals for systemic use. Nucleosides and nucleotides excluding reverse transcriptase inhibitors
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	1×10's, 21's,30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Famvir by M/s Novartis, USFDA Approved.
	For generic drugs (me-too status)	Famvir (Reg.018994) of M/s. Novartis, Pakistan.
	GMP status of the Finished product manufacturer	GMP granted on 10/09/2020 Tablet section approved.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Famciclovir is not present. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies of drug substance	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (FCV20150304), (FCV20150304), (FCV20150304)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is *Viracure 250mg tablet* by ATCO Laboratory by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Viracure 250mg Tablets by ATCO Laboratory in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

Remarks:

STABILITY STUDY DATA			
Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, China		
API Lot No.	20200618		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-007	T-007	T-007
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	15.11.2020	15.11.2020	15.11.2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. JS20180935 issued by CFDA valid till 26/11/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of documents dated 16/07/2020 is submitted wherein the permission to import different APIs including Paroxetine HCl for the purpose of test/analysis and stability studies is granted. • AWB No.157-HKG-2717-3381 dated 16/07/2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [VII]:

S No	Section #.	Deficiencies	Replies
1.	1.6.5	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin is needed	Drug Manufacturing License # 000496 Valid till 3-2022 issued by the DRAP to valor pharma is provided
2.	***3.2.P***	In Pharmaceutical equivalence submit date of analysis, the comparison of the developed formulation was made by using local product viracure of Atco when innovators product by Novartis is available in Pakistan.	As Famvir of Novartis was not available immediately at time of comparative equivalence studies so therefore Viracure of Atco was used. In both the samples and reference products showed more than 85% dissolution are with in first 15 minutes so results are satisfactory
3.	3.2.P.4.5	Regarding query that Excipients of Human or Animal Origin shall be addressed for the use of "Magnesium stearate" in the applied formulation For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE. the firm provided the certificate from "Peter geven" that this magnesium stearate is from plant source	The firm provided the certificate showing that the magnesium stearate is of plant origin.
4.		Composition is different from reference product of USFDA	In innovators formulation sodium lauryl sulphate is not included
5.	***2.3.P.4***	Control of excipients is missing	Provided
6.	***3.2.P.3.4***	Tests and acceptance criteria should be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing	Provided

		process, to ensure that the process is controlled	
7.	3.2.P.5.4	In the specifications of coated tablets for batch T-008 is mentioned as USP but the tablet is not available in monograph	It was a typographical error which is corrected to innovators specification
8.	***3.2.P.6***	COA of primary / secondary reference standard including source and lot number shall be provided	Provided
9.	***3.2.P.8***	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is provided
10.	***3.2.P.8***	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers is provided

Decision of 316:

Deferred for the following

Submission of Comparative dissolution profile (CDP)

For the Clarification of difference in composition from the reference product and submission of compatibility study of excipients since the reference product doesn't contains sodium lauryl sulphate.

Remarks of evaluator:

Justification of Sodium Lauryl Sulphate (SlS) In Valofam 250mg Tablets Formulation

During product development we encountered a problem in the dissolution rate of VALOFAM 250MG TABLETS (Famciclovir), as Famciclovir base is used in the formulation, which has low solubility profile, therefore sodium lauryl sulphate 0.85% has been used in the master formulation to enhance the dissolution profile.

2. The allowable limit for SLS in tablet formulation is 0.5% - 2.5% w/w.
3. So therefore SLS was used according standard formulation protocols.
4. The documentary evidence of Hand book of Pharmaceutical excipients regarding SLS has been attached.
5. Excipients compatibility studies of **VALOFAM** (Famciclovir) 250mg Tablets, has been performed and submitted.

Submission of Comparative dissolution profile (CDP)

Submitted

Decision of 321st meeting: Approved.

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

Case no. 01 Registration applications for local manufacturing of (Human) drugs
a. New cases

23.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Amenor 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Norfloxacin ……400mg
	Diary No. Date of R& I & fee	Dy. No. 12821 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Fluoroquinolones antibacterial
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Norfloxacin-ratiopharm® 400 mg tablets. MHRA approved
	Me-too status	Urac 400mg film-coated Tablets. Reg. No. 64219
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and DML renewal inspection report.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
24.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Ameset 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron as hydrochloride dihydrate …..… 4mg
	Diary No. Date of R& I & fee	Dy. No. 12842 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiemetics and antinauseants
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 4 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 4mg.
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm initially submitted all the documents meant for 8mg strength. Then, revised these for 4mg. • The firm had already adjusted the weight of API in the master formulation. Then, revised "Ondansetron as hydrochloride dihydrate" to Ondansetron hydrochloride dihydrate in master formulation. • The firm submitted Rs. 7500 fee (challan-8412424583)
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared	

	full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
25.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Aqua Pro Injection 10ml
	Composition	Each 10ml Ampoule Contains: Sterile water for injection…10ml
	Diary No. Date of R& I & fee	Dy. No. 12847 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Fluoroquinolones antibacterial
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	25's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sterile water for injection (1ml, 2ml, 3.2ml, 5ml and 10ml) ampule Glass class I. MHRA approved
	Me-too status	Mini Wfi Injection 10ml. Reg. No. 84526
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • You have mentioned filled volume as 10.5ml (extractable volume 10ml), however, you have mentioned 100L for 10,000 ampoules batch. Revised 100 L to 105 L. • The firm was asked to specify the packaging materials. The firm did not specify the primary packaging material. • The firm submitted Rs. 7500 fee (challan-79741570017)
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
26.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Carbaphen 400/325mg Tablet
	Composition	Each Tablet Contains: Methocarbamol……400mg Acetaminophen……325mg
	Diary No. Date of R& I & fee	Dy. No. 12822 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	methocarbamol, combinations excl. psycholeptics.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications. Revised to in-house specs.
	Pack size & Demanded Price	10's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Robaxacet tablet, 325/400mg. Health Canada approved
	Me-too status	Baxamin tablet, 325/400mg. Reg. No. 064558
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report. • Revised the pharmacological group from muscle relaxant + antipyretic to methocarbamol, combinations excl. psycholeptics.

		• The firm submitted Rs. 7500 fee (challan-54841093975)
	Decision: Approved.	
27.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Domcin 15/20 mg Tablet
	Composition	Each Tablet Contains: Domperidone as maleate……15mg Cinnarizine……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 12807 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiemetic and antihistaminic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Dozin Tablets. Reg. No. 033098
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
28.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Ebasin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Ebastine ……10mg
	Diary No. Date of R& I & fee	Dy. No. 12838 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Non-sedating antihistaminic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in JP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EBASTINE ARROW 10 mg film-coated tablets ANSM Approved
	Me-too status	Atmos Tablets 10mg (Reg# 056116)
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Submitted latest GMP inspection report / certificate. • The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with JP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
29.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Epilev 500mg film coated Tablet

	Composition	Each Film Coated Tablet Contains: Levetiracetam ……..…. 500mg
	Diary No. Date of R& I & fee	Dy. No. 12838 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 500 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 500mg Tablets. Reg. No. 84221
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Submitted latest GMP inspection report / certificate. • The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
30.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Fexofed 120mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl……120mg
	Diary No. Date of R& I & fee	Dy. No. 12838 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihistaminic agent, systemic H1 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP, BP and JP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fexofenadine Cipla 120 mg film-coated tablets. **MHRA** approved
	Me-too status	Kovence 120mg Tablets. Reg. No. 33464
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Submitted latest GMP inspection report / certificate. • The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with JP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
31.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Finride 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Finestaride ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 12811 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Testosterone-5-alpha reductase inhibitors

	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP and BP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Finasteride 5 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Finastic Tablets 5mg. Reg. No. 33930
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report. • Revised finestaride to Finasteride. • Revised the pharmacological group from 5-alpha reductase inhibitors to Testosterone-5-alpha reductase inhibitors
	Decision: Registration Board approved registration of product with innovator's specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs	
32.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Histamer 8mg Tablet
	Composition	Each Tablet Contains: Betahistine di hydrochloride ……..…8mg
	Diary No. Date of R& I & fee	Dy. No. 12804 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antivertigo
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP and BP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Betahistine uncoated tablet 8mg. **MHRA** approved
	Me-too status	Vetinil 8mg Tablet. Reg. No. 40956
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Applied for Betahistine di hydrochloride…8mg and mentioned Betahistine di hydrochloride…16mg in the composition. Revised it to 8mg. • The firm submitted Rs. 7500 fee (challan-993244102)
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with JP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
33.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Loratmer 10mg Tablet
	Composition	Each Tablet Contains: Loratadine ……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 12815 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	antihistamines for systemic use
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Loratadine 10 mg uncoated tablet. **MHRA** approved
	Me-too status	Loren Tablets 10mg. Reg. No. 41496
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Revised the pharmacological group from antiallergic to antihistamines for systemic use.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
34.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Mebspa 135mg Tablet
	Composition	Each Film Coated Tablet Contains: Mebeverine HCl ……..…. 135mg
	Diary No. Date of R& I & fee	Dy. No. 12816 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specifications.
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	COLESE mebeverine hydrochloride 135mg tablet film-coated. **TGA** approved
	Me-too status	Mebofac Tablets 135mg film-coated. Reg. No. 74267
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Revised the pharmacological group from antispasmodic, antichlenergic to Drugs for functional gastrointestinal disorders.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
35.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Pantrop 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Pantoprazole as sodium sesquihydrate……20mg
	Diary No. Date of R& I & fee	Dy. No. 12844 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP.
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROTONIX (pantoprazole sodium) delayed-release tablets 20mg, for oral use. USFDA approved
	Me-too status	Qtum Tablet 20mg. Reg. No. 82647
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Submitted latest GMP inspection report / certificate.

		• The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
36.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Piopride Forte Tablet 30/4mg
	Composition	Each Tablet Contains: Pioglitazone……..30mg Glimepiride……4mg
	Diary No. Date of R& I & fee	Dy. No. 12824 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	3x10's, 14's, 2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	DUETACT (pioglitazone and glimepiride) tablets uncoated (30mg/2mg, 30mg/4mg). USFDA approved
	Me-too status	Zoliget Tablet. Reg. No. 50714
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Had already adjusted the weight of Pioglitazone HCl in the composition as per salt factor. Revised Pioglitazone…30mg to Pioglitazone as HCl…30mg in Form 5. • Revised the pharmacological group from oral antihyperglycemic drugs to Combinations of oral blood glucose lowering drugs. • Submitted Rs. 7500 (challan- 13374174663)
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
37.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Rostan 10mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin as calcium ……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 12827 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Crestor 10mg film-coated tablets. MHRA approved
	Me-too status	Rosan 10mg Tablet. Reg. No. 81462
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,

	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Had already mentioned film-coated tablet in the compostion. Revised the label claim in Form 5 to each film-coated tablet contains. • Revised the pharmacological group from oral antihyperglycemic drugs to Combinations of oral blood glucose lowering drugs. • Submitted Rs. 7500 (challan- 13007519) **Revised label claim is as under;** **Each film coated Tablet Contains:** **Rosuvastatin as calcium ……..…10mg**
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
38.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Rostan 20mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin as calcium ……20mg
	Diary No. Date of R& I & fee	Dy. No. 12828 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Crestor 20mg film-coated tablets. MHRA approved
	Me-too status	Rostat 20mg Tablet. Reg. No. 55731
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Had already mentioned film-coated tablet in the composition. Revise the label claim in Form 5 to each film-coated tablet contains. • Revise the pharmacological group from oral antihyperglycemic drugs to Combinations of oral blood glucose lowering drugs. • Submitted Rs. 7500 (challan- 2558014661) **Revised label claim is as under;** **Each film coated Tablet Contains:** **Rosuvastatin as calcium ……..…20mg**
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
39.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Rostan 5mg Tablet

	Composition	Each Tablet Contains: Rosuvastatin as calcium ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 12840 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Crestor 5mg film-coated tablets. MHRA approved
	Me-too status	Rostat 5mg Tablet. Reg. No. 55729
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report. • Had already mentioned film-coated tablet in the compostion. Revise the label claim in Form 5 to each film-coated tablet contains. • Had applied for 5mg tablet and the composition depicted the same, but the label claim in Form 5 was Rosuvastatin as calcium…10mg. Revised it to 5mg. • Revised the pharmacological group from oral antihyperglycemic drugs to Combinations of oral blood glucose lowering drugs. • Submitted Rs. 7500 (challan- 427728038476) **Revised label claim is as under;** **Each film coated Tablet Contains:** **Rosuvastatin as calcium ……..…5mg**
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
40.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Solifen 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 12830 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Drugs for urinary frequency and incontinence.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Solifenacin succinate 5 mg film-coated tablets (Each film-coated tablet contains 5 mg solifenacin succinate, corresponding to 3.8 mg solifenacin). MHRA approved
	Me-too status	Solina 5mg Tablet. Reg. No. 61212
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Revised the pharmacological group from competitive muscarinic receptor antagonist to Drugs for urinary frequency and incontinence.

	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with innovator's specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	
41.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Tizadin 2mg Tablet
	Composition	Each Tablet Contains: Tizanidine as HCl ……2mg
	Diary No. Date of R& I & fee	Dy. No. 12832 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tizanidine (as HCl) 2 mg Tablets. MHRA approved
	Me-too status	Mylex Tablets 2mg. Reg. No. 63031
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Revised the pharmacological group from alpha-2 receptor antagonist to Muscle relaxants, centrally acting agents.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
42.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Vastamer 10mg Tablet
	Composition	Each Tablet Contains: Atorvastatin as calcium ……10mg
	Diary No. Date of R& I & fee	Dy. No. 12802 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
	Me-too status	Torvia 10mg Tablet by Pakistan Pharmaceutical Products. Reg. No. 81162
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Had already adjusted the weight of API as per salt factor. The reference product in Health Canada contains Atorvastatin as calcium trihydrate. Revised the label claim from Atorvastatin as calcium to Atorvastatin as calcium trihydrate, and Atorvastatin calcium to Atorvastatin calcium trihydrate in the master formula.

		• Submitted Rs. 7500 (challan- 1338134663)
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product as per following label claim: **"Each film coated tablet Contains:** **Atorvastatin as calcium ……10mg"** **Firm shall submit revised label claim along woth master formulation for film coated tablet alongwith fee of Rs. 7,500/- for correction/pre-approval change/ in product label clam frm uncoated to film coated tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
43.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Vastamer 40mg Tablet
	Composition	Each Tablet Contains: Atorvastatin as calcium ……..…40mg
	Diary No. Date of R& I & fee	Dy. No. 12801 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
	Me-too status	Fatilor 40mg Tablet by Lisko Pakistan Ltd. Reg No. 58163 (does not depict film-coating)
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report. • Had already adjusted the weight of API as per salt factor. The reference product in Health Canada contains Atorvastatin as calcium trihydrate. Revised the label claim from Atorvastatin as calcium to Atorvastatin as calcium trihydrate, and Atorvastatin calcium to Atorvastatin calcium trihydrate in the master formula. • Submitted Rs. 7500 (challan- 10165654)
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product as per following label claim: **"Each film coated tablet Contains:** **Atorvastatin as calcium ……10mg"** • **Firm shall submit revised label claim along woth master formulation for film coated tablet alongwith fee of Rs. 7,500/- for correction/pre-approval change/ in product label clam frm uncoated to film coated tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
44.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Zematin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine HCl ……..…10mg

	Diary No. Date of R& I & fee	Dy. No. 12817 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Memantine 10 mg film-coated tablets by Aristo Pharma GmbH. Approved by MHRA
	Me-too status	Memlip 10mg Tablets by WnsFeild Pharmaceuticals. Hattar. Reg. No. 84222
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt.) Limited in fee challan and GMP inspection report. • Revised the pharmacological group from NMDA receptor antagonist to anti-dementia drugs.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
45.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Fibret 100mg Capsule
	Composition	Each Capsule Contains: Fenofibrate ……..…. 100mg
	Diary No. Date of R& I & fee	Dy. No. 12045 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Fibrates
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	LIPOMIN CAP 100mg. Reg. No. 10601
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to revise the pharmacological group to fibrates. The firm did not comply. • The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • The reference product in USFDA contains micronized fenofibrate. The firm was asked to revise it accordingly. The firm did not comply. • Submitted Rs. 7500 (challan-925973487112) • The provided reference was discontinued in USFDA. Provide proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of Registration Board.
	Decision: Deferred for the following:	

	• **Revision of pharmacological group of the applied formulation.** • **Type of the capsule shell materials in the composition/master formula.** • **Clear manufacturing outlines of the applied formulation.** • **Latest GMP certificate/inspection report conducted within last three years.** • **Evidence of approval of applied formulation in reference regulatory authorities as defined in 275th meeting of Registration Board.**	
46.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Fibret 134mg Capsule
	Composition	Each Capsule Contains: Fenofibrate (micronized) …. 134mg
	Diary No. Date of R& I & fee	Dy. No. 12046 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Fibrates
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ticor 134mg capsule (micronized). Not discontinued or withdrawn for safety or effectiveness reasons in USFDA
	Me-too status	Fenoget 134mg Capsule. Reg. No. 55692
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to revise the pharmacological group to fibrates. The firm did not comply. • The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • The reference product in USFDA contains micronized fenofibrate. The firm revised it accordingly. • Submitted Rs. 7500 (challan-2323528893)
	Decision: Approved with USP specifications. Registration letter will be issued after submission of type of the capsule shell materials in the composition/master formula, revision of pharmacological group, clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
47.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Itazon 100mg Capsule
	Composition	Each Capsule Contains: Itraconazole …… 100mg
	Diary No. Date of R& I & fee	Dy. No. 12047 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Triazole and tetrazole derivatives.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	1x4's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ITRACONAZOLE 100mg Capsules. MHRA approved
	Me-too status	Soprazole-100mg Capsules. Reg. No. 29044

	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to revise the pharmacological group to Triazole and tetrazole derivatives. The firm did not comply. • The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan-2323528893) • The firm submitted the composition, label claim and manufacturing outlines for fenofibrate capsule. Then, revised it.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of type of the capsule shell materials in the composition/master formula, revision of pharmacological group, clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
48.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Pregab 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin …… ..… 100mg
	Diary No. Date of R& I & fee	Dy. No. 12038 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lyrica 100 mg hard capsules (**EMA** Approved)
	Me-too status	Gabica 100mg Capsules by Getz Pharma
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan- 973640693)
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
49.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Pregab 150mg Capsule
	Composition	Each Capsule Contains: Pregabalin ……..… 150mg
	Diary No. Date of R& I & fee	Dy. No. 12039 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019

	Pharmacological Group	Antiepileptic's
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pregabalin Noumed 150 mg capsules. MHRA Approved
	Me-too status	Gabica 150mg Capsules by Getz Pharma. Reg. No. 48724
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan- 162656484753)
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
50.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Pregab 50mg Capsule
	Composition	Each Capsule Contains: Pregabalin …… ..… 50mg
	Diary No. Date of R& I & fee	Dy. No. 12036 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 50 mg Capsules, Hard. MHRA approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan- 83481165734)
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
51.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Pregab 75mg Capsule
	Composition	Each Capsule Contains: Pregabalin ……..… 75mg
	Diary No. Date of R& I & fee	Dy. No. 12037 dated 06.03.2019

		Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 75 mg Capsules, Hard. MHRA approved
	Me-too status	Scirica 75mg Capsule. Reg. No. 82186
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan- 544681627)
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of type of the capsule shell materials in the composition/master formula, clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
52.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	TEGAP 100mg Capsule
	Composition	Each Capsule Contains: Gabapentin ……..…… 100mg
	Diary No. Date of R& I & fee	Dy. No. 12041 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Gabapentin 100mg Capsules. MHRA approved
	Me-too status	Pentowan 100mg Capsule. Reg. No. 79688
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan- 1606221893)
	Decision: Approved with USP specifications. Registration letter will be issued after submission of clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
53.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	TEGAP 300mg Capsule

	Composition	Each Capsule Contains: Gabapentin …… 300mg
	Diary No. Date of R& I & fee	Dy. No. 12042 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Gabapentin 300mg Capsules. MHRA approved
	Me-too status	Pentowan 300mg Capsule. Reg. No. 82103
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan- 36131326)
	Decision: Approved with USP specifications. Registration letter will be issued after submission of clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
54.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	TEGAP 400mg Capsule
	Composition	Each Capsule Contains: Gabapentin…… 400mg
	Diary No. Date of R& I & fee	Dy. No. 12043 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Gabapentin 400mg Capsules. MHRA approved
	Me-too status	NEURONTIN CAPSULES 400mg. Reg. No. 16141
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply. • The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan- 19284183)
	Decision: Approved with USP specifications. Registration letter will be issued after submission of clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	

55.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Tremsin Capsule 0.4mg
	Composition	Each Capsule Contains: Tamsulosin HCl (As Modified Release Pellets) Eq. To Tamsulosin …. 0.4mg
	Diary No. Date of R& I & fee	Dy. No. 12044 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Alpha-1 blocking agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use. **USFDA** approved
	Me-too status	Tamsolin 0.4mg Capsule. Reg. No. 50392
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add capsule sealing process in the manufacturing outlines. • The firm was asked to provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. The firm submitted the source of pellets as M/s Vision Pharmaceuticals. • Submitted Rs. 7500 (challan-84886916)
	Decision: Approved with BP specifications. Registration letter will be issued after submission of Latest GMP certificate/inspection report conducted within last three years.	
56.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Tritamol 50mg Capsule
	Composition	Each Capsule Contains: Tramadol Hydrochloride …… 50mg
	Diary No. Date of R& I & fee	Dy. No. 12034 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	other opioids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tramadol 50 mg Capsules. MHRA approved
	Me-too status	Campex 50mg Capsule. Reg. No. 075893
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• The firm was asked to revise the pharmacological group from non-narcotic analgesic to other opioids. The firm did not comply. • Had submitted the composition, label claim and manufacturing outlines for fenofibrate capsule. Then, revised it. • The firm was asked to specify the capsule shell materials in the composition/master formula. The firm did not comply.

		• The firm was asked to submit clear manufacturing outlines. The firm did not comply. • Submitted Rs. 7500 (challan-844031114)
	Decision: Approved with BP specifications. Registration letter will be issued after submission clear manufacturing outlines and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
57.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Trestat 120mg Capsule
	Composition	Each Capsule Contains: Orlistat ……..….. 120mg
	Diary No. Date of R& I & fee	Dy. No. 12040 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Peripherally acting antiobesity products
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	XENICAL 120mg Hard Gelatin Capsule, CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24 17489 Greifswald Germany
	Me-too status	Orlifit 120mg capsule. Reg. No. 058474
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signature of the production manager is placed on the file.
		• Revise the pharmacological group to Peripherally acting antiobesity products. • Revise the label claim from "Orlistat…..120mg" to "Orlistat IR pellets equivalent to Orlistat……120mg". • Specify the capsule shell materials in the composition/master formula. • Revise orlistat to Orlistat IR pellets in the composition and adjust its weight as per strength of the pellets. • Add capsule sealing process in the manufacturing outlines. • Clarify the use of excipients in the composition. • Provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets along with other requirements. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Submission of source of pellets in which stability studies of the pellets have been conducted at real time conditions i.e., 30°C ± 2°C/65% RH ± 5% RH along with quantification of degradation products throughout the stability studies / assigned shelf life.** • **Revision of the pharmacological group to Peripherally acting antiobesity products.** • **Revision of the label claim from "Orlistat…..120mg" to "Orlistat IR pellets equivalent to Orlistat……120mg.** • **Specify the capsule shell materials in the composition/master formula.**	

	• **Revise orlistat to Orlistat IR pellets in the composition and adjust its weight as per strength of the pellets.** • **Add capsule sealing process in the manufacturing outlines.** • **Clarify the use of excipients in the composition.** • **Provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets along with other requirements.** • **For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
58.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Cefifort 250mg Injection
	Composition	Each Vial Of Dry Substance Contains: Sterile Ceftazidime As (Pentahydrate) ……..… 250mg
	Diary No. Date of R& I & fee	Dy. No. 12033 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. available in USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fortum® 250 mg powder for solution for injection (vial). MHRA approved
	Me-too status	Fortez Injection 250mg IM/IV. Reg. No. 82751
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The reference product contains sodium bicarbonate as excipient. The firm did not mention it. The firm mentioned it later. • Submitted Rs. 7500 (challan- 81517128336)
	Decision: Approved with USP specifications. Registration letter will be issued after submission Latest GMP certificate/inspection report conducted within last three years.	
59.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Cefifort 500mg Injection
	Composition	Each Vial Of Dry Substance Contains: Sterile Ceftazidime As (Pentahydrate) ……..… 500mg
	Diary No. Date of R& I & fee	Dy. No. 12032 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Third-generation cephalosporin.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. available in USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fortum® 500 mg powder for solution for injection (vial). MHRA approved
	Me-too status	Fortez Injection 500mg IM/IV. Reg. No. 82750
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The reference product contains sodium bicarbonate as excipient. The firm did not mention it. The firm mentioned it later. • Submitted Rs. 7500 (challan- 04230334868)
	Decision: Approved with USP specifications. Registration letter will be issued after submission Latest GMP certificate/inspection report conducted within last three years.	

60.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Cefifort 1g Injection
	Composition	Each Vial Of Dry Substance Contains: Sterile Ceftazidime As (Pentahydrate) …… 1g
	Diary No. Date of R& I & fee	Dy. No. 12037 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. available in USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fortum® 1 g powder for solution for injection (vial). MHRA approved
	Me-too status	Fortez Injection 1g IM/IV. Reg. No. 82749
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The reference product contains sodium bicarbonate as excipient. The firm did not mention it. The firm mentioned it later. • Submitted Rs. 7500 (challan- 4543271937)
	Decision: Approved with USP specifications. Registration letter will be issued after submission Latest GMP certificate/inspection report conducted within last three years.	
61.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Gluti Injection 40mg / 0.4mg /4ml
	Composition	Each Ampule Contains: Phloroglucinol Hydarte … 40mg Trimethylphloroglucinol …. 0.04mg
	Diary No. Date of R& I & fee	Dy. No. 12037 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Other drugs for functional gastrointestinal disorders.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	6'sx4ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SPASFON, solution injectable en ampoule (4ml). ANSM approved
	Me-too status	Spadix Injection. Reg. No. 29528
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The firm was asked to revise the pharmacological group from antispasmodic to Other drugs for functional gastrointestinal disorders. The firm did not comply. • Had mentioned both vial and ampoule in packaging. The firm mentioned ampoule later. • Submitted Rs. 7500 (challan- 00764207) 81517128336
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission Latest GMP certificate/inspection report conducted within last three years.	
62.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name +Dosage Form + Strength	Webtum-500mg Injection

	Composition	Each Vial Contains: Cefoperazone Sodium Equivalent To 250mg Of Cefoperazone Sulbactam Sodium Equivalent To 250mg Sulbactam
	Diary No. Date of R& I & fee	Dy. No. 12035 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Third-generation cephalosporins and beta lactams.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed JP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulperazon Injection 0.5 g (0.25g/0.25g). PMDA Approved
	Me-too status	Perabactum Injection 500mg IV/IM. Reg. No. 80380
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The firm was asked to revise the pharmacological group from Third-generation cephalosporins to Third-generation cephalosporins and beta lactams. The firm did not comply. • Had mentioned both vial and ampoule in packaging. The firm mentioned vials later. • The reference product contains pH regulator. The firm was asked to add in the composition accordingly. The firm did not comply. • Submitted Rs. 7500 (challan- 19284183)
	Decision: Approved. Registration letter will be issued after submission of revised pharmacological group, addition of pH regulator in the formulation and Latest GMP certificate/inspection report conducted within last three years alongwith pre-variation registration fee.	
63.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Merop 500mg Injection IV
	Composition	Each Vial Contains: Meropenem As Trihydrate ……500mg
	Diary No. Date of R& I & fee	Dy. No.13076 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Carbapenem
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meropenem 500 mg Powder for Solution for Injection or Infusion. MHRA Approved
	Me-too status	Meroget Powder for Solution for Infusion or Injection. Reg. No. 83174
	GMP status	Nicholas pharma: Firm has submitted copy of GMP certificate dated 25-02-2020 issued on the basis of inspection dated 28-01-2020
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The signature of the signatory on Form 5 for contract manufacturing is different from the other dossiers submitted on the same date.

		• The firm was asked to mention the quantity of sodium carbonate in the composition. The firm submitted that meropenem is a blend with sodium carbonate • Had mentioned both vial and ampoule in packaging. The firm mentioned vials later. • Submitted Rs. 7500 (challan-463238537) Registration Board in its 307th meeting discussed the capacity inspection report in details. Deliberations were made on used and available manufacturing and quality control capacity keeping in view all registered product and currently applied products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad for following sections: • Dry Powder Injection (Cephalosporin) Section • Dry Powder for Suspension (Cephalosporin) Section • Capsule (Cephalosporin) Section • Dry Powder Injection (Carbapenem) Section Lately M/s Nicholas Pharmaceuticals in compliance to the decision of the 307th meeting of Registration Board vide its letter Dy. No. 6357 dated 08-03-2022 submittted that they have purchased two HPLC systems and submitted its purchase documents including invoice No. RI-22-52 dated 05-01-2022 for Azura Isocratic HPLC system including all accessories and invoice No. TS100-58/22 dated 5th March 2022 for Perkin elmer HPLC with column oven and gradient system.
	Decision: Approved. Registration letter will be issued after submission of Latest GMP certificate/inspection report conducted within last three years of the applicant.	
64.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Merop 1g Injection IV
	Composition	Each Vial Contains: Meropenem As Trihydrate…1g
	Diary No. Date of R& I & fee	Dy. No.13077 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Carbapenem
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meropenem 1g Powder for Solution for Injection or Infusion. MHRA Approved
	Me-too status	Meroget Powder for Solution for Infusion or Injection. Reg. No. 83175
	GMP status	The firm was inspected on 06.11.2018 with satisfactory level of GMP compliance. The firm was inspected on 03.08.2018 with satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The signature of the signatory on Form 5 for contract manufacturing is different from the other dossiers submitted on the same date.

		• The firm was asked to mention the quantity of sodium carbonate in the composition. The firm submitted that meropenem is a blend with sodium carbonate • Had mentioned both vial and ampoule in packaging. The firm mentioned vials later. • Submitted Rs. 7500 (challan-40152207)
	Decision: Approved. Registration letter will be issued after submission of Latest GMP certificate/inspection report conducted within last three years of applicant.	
65.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Brutex 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Ibuprofen ……400mg
	Diary No. Date of R& I & fee	Dy. No. 11721 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Claimed USP specs.
	Pack size & Demanded Price	10x10's, 25x10's, 500's, 1000's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ibuprofen 400mg Tablets film-coated. MHRA approved
	Me-too status	Hebofen 400mg Tablets. Reg. No. 68392
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Stamped signatures of the QCM and PM are placed in the file.
	Decision: Approved.	
66.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	C-Zole 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Clotrimazole ……..…500mg
	Diary No. Date of R& I & fee	Dy. No. 11699 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	Claimed BP specs.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clotrimazole 500mg Vaginal Tablet vaginal. MHRA approved
	Me-too status	Amclotrim Vaginal Tablets 500 mg. Reg. No. 69937
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Stamped signatures of the QCM and PM are placed in the file. • The firm was asked to provide pharmacological group. The firm mentioned it as antivertigo. • Had applied for film-coated tablet, and had mentioned oral route of administration. The international reference product is vaginal tablet. Changed the route to vaginal. Revised the composition and manufacturing outlines meant for uncoated tablet. • Submitted Rs. 7500/- (challan- 01823603453)
	Decision: Approved. Registration letter will be issued after submission of differential fee of Rs. 22,500/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	

	• **Firm will also submit corrected pharmacological group alongwith pre-registration variation fee.**	
67.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Motim 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Domperidone ……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 11673 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Claimed in-house specs. Available in BP
	Pack size & Demanded Price	30's, 50's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Domperidone (as maleate) 10mg Tablets. MHRA approved Domperidone (as maleate) 10mg Film-Coated Tablets. MHRA approved. DOMPERIDONE (base) ALMUS 10 mg film-coated tablets. ANSM approved
	Me-too status	Nendone Tablets 10mg. Reg. No. 29785
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Stamped signatures of the QCM and PM are placed in the file. • Revised the pharmacological group to "propulsives".
	Decision: Approved with BP specificationsand following label claim; **Each Film Coated Tablet Contains:** **Domperidone as maleate ……..…10mg** • **Registration letter will be issued after submission of fee of Rs. 30,000/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Firm will also submit revised label claim as per reference product i.e. Domperidone (as maleate) 10mg Tablets.**	
68.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Panamol 500mg Tablet
	Composition	Each Tablet Contains: Paracetamol ……..…500mg
	Diary No. Date of R& I & fee	Dy. No. 11682 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Analgesics
	Type of Form	Form 5
	Finished Product Specification	Claimed USP specs.
	Pack size & Demanded Price	100's, 200's, 500's, 1000's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paracetamol 500mg Tablets. MHRA approved
	Me-too status	PANADOL TAB. Reg. No. 000817
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Stamped signatures of the QCM and PM are placed in the file.
	Decision: Approved.	
69.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ropim 0.25mg Tablet
	Composition	Each Film Coated Tablet Contains: Ropinirole as Hcl…0.25mg
	Diary No. Date of R& I & fee	Dy. No. 11682 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019

	Pharmacological Group	Antiparkinson
	Type of Form	Form 5
	Finished Product Specification	Claimed USP specs.
	Pack size & Demanded Price	21's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ropinirole 0.25 mg film-coated tablets (as hydrochloride) 1mg. MHRA approved.
	Me-too status	Requip Tablets 0.25mg. 28442
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Scanned signatures of the QCM and PM are placed in the file. • Had already adjusted the weight of API as per salt factor in the master formula. Revised Ropinirole as Hcl to Ropinirole Hcl in the master formula • Submitted Rs. 7500/- (challan- 6531332952)
	Decision: Approved.	
70.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rovit 5% Cream
	Composition	Each Gram Contains: Acyclovir ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 11701 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antivirals
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specs.
	Pack size & Demanded Price	2g, 5g, 10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZOVIRAX® (acyclovir) cream, for topical use 5%. USFDA approved.
	Me-too status	Ciavir 5% Cream. Reg. No. 85089
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Scanned signatures of the QCM and PM are placed in the file. • Had not mentioned sealing of tubes in the manufacturing outlines. Revised it.
	Decision: Approve. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
71.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Texklar XR 500mg Tablet
	Composition	Each Extended Release Film Coated Tablet Contains: Clarithromycin ……..…500mg
	Diary No. Date of R& I & fee	Dy. No. 11672 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Macrolide
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	5's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Klaricid XL 500 mg Tablets film-coated. MHRA approved.
	Me-too status	Canter-OD Tablet 500 mg film-coated (extended release). Reg. No. 82133
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Scanned signatures of the QCM and PM are placed in the file.

	Decision: Approved.	
72.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	V-Fox 50mg Tablet
	Composition	Each Uncoated Tablet Contains: Venlafaxine as HCl ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 11724 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	N06A Antidepressants.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Venlafaxine (as hydrochloride) uncoated tablet (25 mg, 37.5 mg, 50 mg, 75 mg, 100 mg). USFDA approved
	Me-too status	Venix Tablets 75mg. Reg. No. 32563
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Scanned signatures of the QCM and PM are placed in the file.
	Decision: Approved.	
73.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	V-Fox 75mg Tablet
	Composition	Each Uncoated Tablet Contains: Venlafaxine as HCl ……..…75mg
	Diary No. Date of R& I & fee	Dy. No. 11723 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	N06A Antidepressants.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Venlafaxine (as hydrochloride) uncoated tablet (25 mg, 37.5 mg, 50 mg, 75 mg, 100 mg). USFDA approved
	Me-too status	Venix Tablets 75mg. Reg. No. 32564
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Scanned signatures of the QCM and PM are placed in the file.
	Decision: Approved.	
74.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Zentex 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Ranitidine as HCl ……150mg
	Diary No. Date of R& I & fee	Dy. No. 11723 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	H2-receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zantac Tablets 150 mg, uncoated. MHRA approved
	Me-too status	Monocid Tablets 150mg. Reg. No. 32828
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• Scanned signatures of the QCM and PM are placed in the file.

		• Revised the pharmacological group from H2 blockers to H2-receptor antagonists.
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products.	
75.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Brimon Eye Drops 10mg/5ml
	Composition	Each ml contains: Brimonidine tartrate ……..…2mg
	Diary No. Date of R& I & fee	Dy. No. 11938 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Sympathomimetics in glaucoma therapy
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed In-house specs. Available in USP.
	Pack size & Demanded Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alphagan 0.2% w/v (2 mg/ml) eye drops, solution. Approved in MHRA
	Me-too status	Alzagan Ophthalmic solution. Reg. No. 82055
	GMP status	The firm was inspected on 16.11.2018, wherein the FIDreported average level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• Had referred to Form 5D in the cover letter, while the submitted enclosure and data as per Form 5. Revised the cover letter. • The reference product contains benzalkonium chloride as microbial preservative, and water for injection. The firm did not mention the same. The firm revised the formulation. Moreover, the firm removed potassium chloride and calcium chloride as alkalinizing agents. • Revised the master formula /batch size as per 5 ml pack size. • Had claimed filled volume of 5ml, but the claimed bottle is 4ml. revised it 5ml. • Submitted Rs. 10000 as differential fee (challan-34537381)
	Decision: Approved with innovator specifications. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
76.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Allop Tablet 300mg
	Composition	Each tablet contains: Allopurinol……..…300mg
	Diary No. Date of R& I & fee	Dy. No. 11947 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	antigout
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	ALLOPURINOL- allopurinol tablet, 300mg (uncoated). Approved in USFDA.
	Me-too status	Alzagan Ophthalmic solution. Reg. No. 82055
	GMP status	The firm was inspected on 16.11.2018, wherein the FID reported average level of GMP compliance.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• Added blistering and packing steps to the manufacturing outlines • Submitted Rs. 10000 as differential fee (challan-753575439)
	Decision: Approved. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
77.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Everos Tablet 0.25mg
	Composition	Each Tablet Contains: Everolimus …….… 0.25 mg
	Diary No. Date of R& I & fee	Dy. No. 11956 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Antineoplastic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	30's, 90's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Certican 0.25 mg tablets, uncoated. MHRA approved.
	Me-too status	Certican tablet 0.25mg. Reg. No. 044829
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• Provide proof of me-too product (name and registration) already approved by DRAp; otherwise, submit your application on Form 5D along with stability data and fee applicable as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Added blistering and packing steps to the manufacturing outlines • Submitted Rs. 10000 as differential fee (challan-972245896)
	Decision: Registration Board considering the fact that Everolimus belongs to both "L01-Antineoplastic" and "L04-Immunosuppressant" class of drug hence deferred for further deliberation regarding its manufacturing requirement.	
78.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Everos Tablet 2.5mg

	Composition	Each Tablet Contains: Everolimus …… 2.5 mg
	Diary No. Date of R& I & fee	Dy. No. 11956 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Antineoplastic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	30's, 90's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Everolimus Sandoz 2.5 mg Tablets, uncoated. MHRA approved.
	Me-too status	AFINITOR 2.5MG TABLETS. Reg. No. 78105
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• Added blistering and packing steps to the manufacturing outlines • Submitted Rs. 10000 as differential fee (challan-13078284773)
	Decision: Registration Board considering the fact that Everolimus belongs to both "L01-Antineoplastic" and "L04-Immunosuppressant" class of drug hence deferred for further deliberation regarding its manufacturing requirement.	
79.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Talim ER Tablet 1mg
	Composition	Each extended release tablet contains: Tacrolimus …… 1mg
	Diary No. Date of R& I & fee	Dy. No. 11952 dated 06.03.2019 Rs.50,000/- dated 06.03.2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	30's, 60's, 90's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ENVARSUS XR® (tacrolimus extended-release tablets), uncoated 1mg. USFDA approved.
	Me-too status	
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• The firm was asked to add blistering and packing steps to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply • The firm was asked to submit stability data as per zone IV-A. The firm informed that they will submit the data. • The firm was asked to revise tacrolimus to tacrolimus monohydrate in the master formula and adjust its

		weight in master formula based on salt factor along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply.
	Decision: Deferred for submission of stability study data as data as per the guidelines approved in 293rd meeting of Registration Board.	
80.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Talim ER Tablet 0.75mg
	Composition	Each extended release tablet contains: Tacrolimus …… 0.75mg
	Diary No. Date of R& I & fee	Dy. No. 11953 dated 06.03.2019 Rs.50,000/- dated 06.03.2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	30's, 60's, 90's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ENVARSUS XR® (tacrolimus extended-release tablets), uncoated 0.75mg. USFDA approved.
	Me-too status	
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• The firm was asked to add blistering and packing steps to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply • The firm was asked to submit stability data as per zone IV-A. The firm informed that they will submit the data. • The firm was asked to revise tacrolimus to tacrolimus monohydrate in the master formula and adjust its weight in master formula based on salt factor along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply
	Decision: Deferred for submission of stability study data as data as per the guidelines approved in 293rd meeting of Registration Board.	
81.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	APRANT 125mg Capsule
	Composition	Each Hard Capsule Contains: Aprepitant …….. 125mg
	Diary No. Date of R& I & fee	Dy. No. 11983 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Antiemtic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	2's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Aprepitant 125 mg hard capsules. MHRA approved.
	Me-too status	Aprant 125 mg Capsule. Reg. No. 82251
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• Added blistering and packing steps to the manufacturing outlines • Submitted Rs. 10000 as differential fee (challan-14771025235) • Revised the quanitity of API in the master formula based on label claim and batch size.
	Decision: Approved. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
82.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	APRANT 40mg Capsule
	Composition	Each Hard Capsule Contains: Aprepitant ……..….. 40mg
	Diary No. Date of R& I & fee	Dy. No. 11984 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Antiemtic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	2's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Emend 40mg hard capsules. USFDA "Federal Register determined that product was not discontinued or withdrawn for safety or effectiveness reasons".
	Me-too status	Apritus 40mg Capsule. Reg. No. 74885
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• Added blistering and packing steps to the manufacturing outlines • Submitted Rs. 10000 as differential fee (challan-0912079527)
	Decision: Approved. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
83.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	APRANT 125mg Sachet (powder for oral suspension)
	Composition	Each sachet contains: Aprepitant …….. 125mg
	Diary No. Date of R& I & fee	Dy. No. 11963 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Antiemtic
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMEND for oral suspension 125mg per pouch. USFDA approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• The firm was asked to clarify the 206kg batch size in terms of number of sachets and calculations of API and excipients thereof, and in case of revision, revise the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply • The firm was asked to add sachet filling, sealing and packing steps to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply • The firm submitted that stability studies are under process
	Decision: Deferred for submission of stability study data as data as per the guidelines approved in 293rd meeting of Registration Board.	
84.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Piram 400mg Capsule
	Composition	Each Capsule Contains: Piracetam …… 400mg
	Diary No. Date of R& I & fee	Dy. No. 11935 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Nootropic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Apritus 40mg Capsule. Reg. No. 74885
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• The firm was asked to provide proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board. The firm did not comply

		• The firm was asked to add blistering and packing steps to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
85.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Piram 1000mg/5ml injection (IV)
	Composition	Each ml Contains: Piracetam ……..…. 200mg
	Diary No. Date of R& I & fee	Dy. No. 11937 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Nootropic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	1x4's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Neurotam Injection 1000mg/5ml. Reg. No. 73480
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• The firm was asked to provide proof of international availability of same formulation, same filled volume and same strength in reference regulatory authorities as defined in 275th meeting of the registration board. The firm did not comply • The firm was asked to provide add packing step to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
86.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Piram 800mg Tablet
	Composition	Each Tablet Contains: Piracetam ……. 800mg
	Diary No. Date of R& I & fee	Dy. No. 11936 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Nootropic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	30's, 90's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piracetam 800mg film-coated tablet. MHRA approved
	Me-too status	Nootropil Tablet 800mg. Reg. No. 82277
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people

		met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• Had mentioned the dosage form as capsule in enclosure of Form 5. The label claim was "each tablet contains". Had mentioned the coating composition in the master formula. **The firm revised the label claim to:** **Each film-coated tablet Contains:** **Piracetam …. 800mg** • Added blistering and packing steps to the manufacturing outlines • Submitted Rs. 10000 as differential fee (challan-06206784120).
	Decision: Approved with innovator's specifications and following label claim; **Each film-coated tablet Contains:** **Piracetam …… 800mg**	
87.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Citolin 1g/4ml Injection
	Composition	Each 4ml Injection Contains: Citicoline sodium Eq. to Citicoline …. 1g
	Diary No. Date of R& I & fee	Dy. No. 11943 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Psychoanaleptic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Innovator's specs.
	Pack size & Demanded Price	5's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Coleen Injection 1000mg/4ml. Reg. No. 46760
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• The firm was asked to provide proof of international availability of same formulation, same filled

		volume and same strength in reference regulatory authorities as defined in 275th meeting of the registration board. The firm did not comply • The firm was asked to clarify the 10L batch size for 5,000 ampule (4ml) and calculations of API and excipients thereof. In case of revision, revise the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply • The firm was asked to add packing step to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Addition of packing step to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
88.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Citolin 250mg/2ml Injection
	Composition	Each 2ml Injection Contains: Citicoline sodium Eq. to Citicoline …. 250mg
	Diary No. Date of R& I & fee	Dy. No. 11944 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Psychoanaleptic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Innovator's specs.
	Pack size & Demanded Price	5's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Citograin Injection 250mg/2ml. Reg. No. 50042
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML
		• The firm was asked to provide proof of international availability of same formulation, same filled volume and same strength in reference regulatory authorities as defined in 275th meeting of the registration board. The firm did not comply. • The firm was asked to provide add packing step to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-

		B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm did not comply
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Addition of packing step to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
89.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Medop Tablet
	Composition	Each Film Coated Tablet Contains: Methyldopa Equivalent To Anhydrous Methyldopa … 250mg
	Diary No. Date of R& I & fee	Dy. No. 11972 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Antihypretensive
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aldomet film-caoted tablets 250mg. MHRA approved
	Me-too status	Aldomet by OBS Pakistan.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML. • The firm has mentioned Cilostazole instead of Cilostazol.
		• The provided label claim is "Methyldopa Equivalent To Anhydrous Methyldopa … 250mg". the firm was asked to mention the hydrate form of the API along with adjustment of its weight based on equivalency factor in master formula with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. The firm mentioned sesquihydrate (1.5 H_2O) form in justification and revised weight of API based on equivalency factor in master formula, but it is still anhydrous in the master formula. • The firm added blistering and packing steps to the manufacturing outlines. • Submitted Rs. 10000 as differential fee (challan-10296563229)
	Decision: Approved. Registration letter will be issued after submission of differential fee of Rs. 20,000/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	

90.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Siltaz 100mg Tablet
	Composition	Each Tablet Contains: Cilostazole ……..….. 100mg
	Diary No. Date of R& I & fee	Dy. No. 11972 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Antiplatelet agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed In-house specs.
	Pack size & Demanded Price	14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cilostazol Tablets 100 mg. PMDA approved
	Me-too status	Kladica Tablet 100 mg. Reg. No. 76638
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML. • The firm has mentioned Cilostazole instead of Cilostazol.
		• Added blistering and packings step to the manufacturing outlines. • Submitted Rs. 10000 as differential fee (challan-7691744945).
	Decision: Approved with USP specifications.	
91.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Velzib 10mg Tablet
	Composition	Each film-coated tablet Contains: Valdecoxib …… 10mg
	Diary No. Date of R& I & fee	Dy. No. 11942 dated 06.03.2019 Rs.20,000/- dated 06.03.2019
	Pharmacological Group	Antiinflamatory
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed In-house specs.
	Pack size & Demanded Price	2's, 5's, 10's, 20's 30's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ulxib 10Mg Tablets. Reg. No. 37069
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi,

		Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML.
		• The firm was asked to provide proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board. The firm provide reference which was discontinued in USFDA. • Added blistering and packings step to the manufacturing outlines. • Submitted Rs. 10000 as differential fee (challan-1728314772
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
92.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	D-40000 Capsules
	Composition	Each Capsule Contains: Cholecalciferol …. 1mg (40,000IU)
	Diary No. Date of R& I & fee	Dy. No. 11979 dated 06.03.2019 Rs.50,000/- dated 06.03.2019
	Pharmacological Group	Vitamins
	Type of Form	Form 5D
	Finished Product Specification	The firm has claimed innovator's specs. Available in USP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Plenachol D3 40 000 IU (equivalent to 1.0 mg vitamin D3) hard Capsules. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML.
		• The firm has applied for hard gelatin capsule, while the reference product is hypromelluse hard capsule. The firm shall revise the formulation in line with the reference product along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.

		• The firm shall add blistering and packings step to the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • The firm shall submit stability data as per zone IV-A.
	Decision: Deferred for the following: • **Provide evidence of approval of applied formulation already approved by the Registration Board with brand name & registration number or elsewise applied on the prescribed form i.e. Form 5D along with applicable fee.** • **Submission of stability data as per guidelines of 293rd meeting of Registration Board.** • **latest GMP certificate/last inspection report conducted within last three years.**	
93.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Hypin 10mg Tablet
	Composition	Each Film-Coated Tablet Contains: Lercanidipine Hydrochloride……. …. 10mg
	Diary No. Date of R& I & fee	Dy. No. 11986 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	7's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lercanidipine Hydrochloride10 mg film-coated tablet. MHRA approved
	Me-too status	Karman-10 Tablets (Lercanidipine HCl eq. to Lercanidipine… 10mg). Reg. No. 38010
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML.
		• Added blistering and packings step to the manufacturing outlines. • Submitted Rs. 10000 as differential fee (challan-9131359212)
	Decision: Approved with innovator's specifications.	
94.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan
	Brand Name +Dosage Form + Strength	Meclan 6.25/25 mcg Capsule
	Composition	Each Capsule Contains: Umeclidinium Bromide Eq. To Umeclidinium … 62.5Mcg Vlinaterol Trifenatate Eq. To Vilanterol …. 25Mcg
	Diary No. Date of R& I & fee	Dy. No. 11986 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.

	Pack size & Demanded Price	7's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lercanidipine Hydrochloride10 mg film-coated tablet. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in Form 5 is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi 75190, Pakistan, Pakistan, while it is Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi in the DML.
		• The firm has applied for hard gelatin capsule, while the reference product is ANORO ELLIPTA is a light grey and red plastic inhaler containing 2 foil blister strips. Each blister on one strip contains a white powder mix of micronized umeclidinium bromide (74.2 mcg equivalent to 62.5 mcg of umeclidinium), magnesium stearate (75 mcg), and lactose monohydrate (to 12.5 mg), and each blister on the other strip contains a white powder mix of micronized vilanterol trifenatate (40 mcg equivalent to 25 mcg of vilanterol), magnesium stearate (125 mcg), and lactose monohydrate (to 12.5 mg). After the inhaler is activated, the powder within both blisters is exposed and ready for dispersion into the airstream created by the patient inhaling through the mouthpiece. The firm shall revise the formulation in line with the reference product. The firm revised the formulation. • Revised the quantity of vilanterol trifenatate based on the salt factor / equivalency in the master formula. • Added blistering and packing steps to the manufacturing outlines. • Submitted Rs. 10000 as differential fee (challan-5382568405) • The firm was asked to provide proof of me-too product approved by DRAP; otherwise, submit stability data as per zone IV-A on Form 5D and differential fee. The firm did not comply.
	Decision: Deferred for the following: • **Provide evidence of approval of applied formulation already approved by the Registration Board with brand name & registration number or elsewise applied on the prescribed form i.e. Form 5D along with applicable fee.** • **Submission of stability data as per guidelines of 293rd meeting of Registration Board.** • **Latest GMP certificate/last inspection report conducted within last three years.**	
95.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Acyclowel 200mg/5ml oral suspension
	Composition	Each 5ml Contains: Acyclovir ……200mg
	Diary No. Date of R& I & fee	Dy. No.12353 dated 06.03.2019

		Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antivirals
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zovirax 200 mg/5 mL oral suspension. HPRA Approved
	Me-too status	Acovir **Dry** Suspension. Reg. No. 84093.
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected, the people met and documentation reviewed and considering the findings of inspection, M/s Welmed Pharmaceutical Industries (Pvt.) Ltd. Gadoon-Swabi is considered to be operating at fair level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group to antivirals. • Added filling and packing process in the manufacturing outlines. • Submitted Rs. 7500/- fee. (Challan-82115071359)
	Decision: Approved.	
96.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Acyclowel 400mg tablet
	Composition	Each film-coated tablet Contains: Acyclovir……400mg
	Diary No. Date of R& I & fee	Dy. No.12394 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aciclovir 400mg tablets**,** uncoated. MHRA Approved
	Me-too status	Virocil 400mg Tablet. Reg. No. 83709
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected, the people met and documentation reviewed and considering the findings of inspection, M/s Welmed Pharmaceutical Industries (Pvt.) Ltd. Gadoon-Swabi is considered to be operating at fair level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the formulation (label, composition and manufacturing outlines) from film-coated tablet to uncoated tablet. • Submitted Rs. 7500/ (Challan- 983111551 **Revised formulation is as under:** **Each tablet Contains:** **Acyclovir……400mg**
	Decision: Approved.	
97.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Tenzex 20mg Tablet

	Composition	Each Film Coated Tablet Contains: Escitalopram as oxalate eq. to escitalopram…20mg
	Diary No. Date of R& I & fee	Dy. No.12350 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	SSRIs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Escitalopram 20 mg film-coated tablets. MHRA approved
	Me-too status	Neolexa 20mg Tablet . Reg. No. 66978
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected, the people met and documentation reviewed and considering the findings of inspection, M/s Welmed Pharmaceutical Industries (Pvt.) Ltd. Gadoon-Swabi is considered to be operating at fair level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Had adjusted the weight of the API in master formulation. • Revised Escitalopram as oxalate to Escitalopram oxalate in master formulation. • Submitted Rs. 7500 (challan- 2153716985)
	Decision: Approved.	
98.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Tenzex 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram as oxalate eq. to escitalopram…5mg
	Diary No. Date of R& I & fee	Dy. No.12351 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	SSRIs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Escitalopram 5 mg film-coated tablets. MHRA approved
	Me-too status	Dipgo Tablet 5mg. Reg. No. 85714
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected, the people met and documentation reviewed and considering the findings of inspection, M/s Welmed Pharmaceutical Industries (Pvt.) Ltd. Gadoon-Swabi is considered to be operating at fair level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Had adjusted the weight of the API in master formulation. • Revised Escitalopram as oxalate to Escitalopram oxalate in master formulation. • Submitted Rs. 7500 (challan-870378719)
	Decision: Approved.	
99.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi

	Brand Name +Dosage Form + Strength	Mopin 2% Cream
	Composition	Each Gram Contains: Mupirocin Calcium Eq. To Mupirocin ……2%
	Diary No. Date of R& I & fee	Dy. No.12355 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Other antibiotics for topical use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SOUL PATTINSON ANTIFUNGAL CLOTRIMAZOLE WOMEN'S TREATMENT 2% w/w vaginal cream tube. **TGA** approved
	Me-too status	Upirox Cream 2%. Reg. No. 82540
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected, the people met and documentation reviewed and considering the findings of inspection, M/s Welmed Pharmaceutical Industries (Pvt.) Ltd. Gadoon-Swabi is considered to be operating at fair level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from antibiotics to Other antibiotics for topical use. • Had adjusted the weight of the API in master formulation. Revised it from 21.36mg to 21.5mg and revised "Mupirocin Calcium Eq To Mupirocin" to Mupirocin Calcium in master formulation. • Did not add filling and packing process in the manufacturing outlines. • Submitted Rs. 7500 (Challan-45284768140).
	Decision: Approved. Firm will also provide revised manufacturing outlines with revision of filling and packing process with applicable pre-registration variation fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
100.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Welpro 800mg/15ml Syrup
	Composition	Each 15ml Contains: Iron protein succinylate 800mg eq. to elemental iron……40mg
	Diary No. Date of R& I & fee	Dy. No.12349 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antianemic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FERPLEX 40 mg Oral Solution (Each vial of 15 ml of oral solution contains: Iron protein succinylate 800 mg (contains milk protein), equivalent to 40 mg of Fe^{3+}). CIMA approved
	Me-too status	Hemiplex Syrup. Reg. No. 057283
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected, the people met and documentation reviewed and considering the findings of inspection, M/s Welmed Pharmaceutical Industries

		(Pvt.) Ltd. Gadoon-Swabi is considered to be operating at fair level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Added packing process in the manufacturing outlines. • In the revised document the label claim is elemental Iron 40mg and protein succinylate 800mg/15ml. The frim once again submitted that the initially submitted label claim may be considered. • Submitted Rs. 7500 (Challan-1375516780)
	Decision: **Deferred for review of applied formulation in line with innovator drug product and generic product.**	
101.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Welzin 20mg/5ml oral syrup
	Composition	Each 5ml Syrup Contains: Zinc Sulphate Monohydrate ……..…20mg
	Diary No. Date of R& I & fee	Dy. No.12352 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Other mineral supplements
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Available in IP as solution (Available strengths: 10 mg or 20 mg of zinc per 5 mL)
	Me-too status	Zevro Syrup 10mg. Reg. No. 77058
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected, the people met and documentation reviewed and considering the findings of inspection, M/s Welmed Pharmaceutical Industries (Pvt.) Ltd. Gadoon-Swabi is considered to be operating at fair level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from trace elements to Other mineral supplements. • Revised the label claim from Zinc Sulphate Monohydrate…20mg to Zinc Sulphate Monohydrate eq to zinc …20mg and adjusted its weight as per salt factor in the master formula. • Added filling and packing process in the manufacturing outlines. • Submitted Rs. 7500 (challan-122735245). Revised label claim is as under: **Each 5ml Syrup Contains:** **Zinc Sulphate Monohydrate eq. to elemental Zinc ……..…20mg**
	Decision: Approved. Registration letter will be issued after submission of differential fee of 22,500/- /- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
102.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Onised 4mg/5ml Syrup
	Composition	Each 5ml Syrup Contains: Ondansetron as HCl Dihydrate ……4mg

	Diary No. Date of R& I & fee	Dy. No.12356 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	50ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron (as the hydrochloride dihydrate) 4mg/5ml Syrup. MHRA Approved
	Me-too status	Ondan syrup 4mg/5ml, Bio-mark pharmaceutical, Reg. No. 082628.
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected, the people met and documentation reviewed and considering the findings of inspection, M/s Welmed Pharmaceutical Industries (Pvt.) Ltd. Gadoon-Swabi is considered to be operating at fair level of compliance with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from selective Serotonin (5HT3) receptor antagonists to Serotonin (5HT3) antagonists. • Had adjusted the weight of the API in master formulation. Revised Ondansetron as HCl dihydrate to Ondansetron HCl dihydrate in master formulation. • Added filling and packing process in the manufacturing outlines. • Submitted Rs. 7500/- fee. (Challan-6223047112)
	Decision: Approved.	
103.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Fast D Tablet 60/120mg
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl……..…60mg Pseudoophedrine HCl……..…120mg
	Diary No. Date of R& I & fee	Dy. No. 12284 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Nasal decongestants for systemic use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA-D 12 HOUR Extended-Release Tablets. USFDA approved
	Me-too status	Fexet-D 60Mg/120Mg film-coated Tablets. Reg No. 39099 (data does not depict two layer tablet)
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator.	• Revised the pharmacological group from antihistamine to antihistamine, Nasal decongestants for systemic use. • Revised the term capsule in the manufacturing outlines to tablet. • Revised each film-caoted tablet to Each extended release tablet. • The manufacturing outlines contained alogliptn and pioglitazone, and capsule. Revised it. • Submitted Rs. 7500/- (Challan- 5244429795)

		• The reference product is in the form of two-layer extended release tablet. Revise the formulation accordingly. • Provide proof of availability of manufacturing facility. • Revise the pseudoephedrine to pseudoephedrine HCl in the recently submitted master formulation.
	Decision: Deferred for the following: • **Revision of formulation as per reference product as the reference product is in the form of two-layer extended release tablet.** • **Revision of label claim from each film-caoted tablet to Each extended release tablet shall be accompanied with full fee instead of 7500/-.** • **Evidence of availability of bilayerd tablet machine.** • **Revision of pseudoephedrine to pseudoephedrine HCl in the recently submitted master formulation.**	
104.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Linzox Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Linezolid ……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 12264 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	1x12's,; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) tablets (film-coated) for oral use by Pharmacia and Upjohn. not discontinued or withdrawn by US-FDA for safety or efficacy reasons
	Me-too status	Enliv 400mg Tablet by PharmEvo (Pvt.) Ltd. Reg No. 58096 (does not depict coating)
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator.	• Revised the pharmacological group from antibiotics to antibacterials. • Revised the term capsule in the manufacturing outlines to tablet. • Did not mention coating composition and coating process. Revised it accordingly. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved. Registration letter will be issued after submission of 7500/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
105.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Linzox Tablet 600mg
	Composition	Each Film Coated Tablet Contains: Linezolid ……..…600mg
	Diary No. Date of R& I & fee	Dy. No. 12265 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	1x12's,; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) 600mg tablets (film-coated) for oral use by Pharmacia and Upjohn. **US-FDA** approved

	Me-too status	Ozlin 600 mg Tablet by Linta Pharmaceuticals. Reg No. 78179
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator.	• Revised the pharmacological group from antibiotics to antibacterials. • Revised the term capsule in the manufacturing outlines to tablet. • Did not mention coating composition and coating process. Revised it accordingly. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved. Registration letter will be issued after submission of 7500/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
106.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	S Vant 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Candesartan Cilexetil ……..…4mg
	Diary No. Date of R& I & fee	Dy. No. 12273 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	1x14's,; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ATACAND® (candesartan cilexetil) non-film-coated tablets, for oral use. USFDA approved
	Me-too status	Ozlin 600 mg Tablet by Linta Pharmaceuticals. Reg No. 78179
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator.	• Revised the pharmacological group from Angiotensin II receptor antagonist to Angiotensin II receptor blockers (ARBs) and diuretics. • Revised the term capsule in the manufacturing outlines to tablet. • Had applied for film-coated tablet without providing coating composition and process. The firm was asked to provide proof of international availability in the reference regulatory agencies as defined by the registration board in its 275th meeting, or revise the formulation to uncoated tablet. The firm did not comply. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also submit revised form 5, its annexures and label claim as uncoated tablets as per reference product and submission of pre-registration variation fee.**	
107.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Savantazide Tablet 16mg/12.5mg
	Composition	Each Film Coated Tablet Contains: Candesartan Cilexetil…16mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy. No. 12275 dated 06.03.2019

		Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	2x14's,; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan and Hydrochlorothiazide 16 mg/12.5 mg Tablets, uncoated. MHRA approved
	Me-too status	Carac-H Tablet 16/12.5mg. Reg No. 55803
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator.	• Revised the pharmacological group from angiotensin receptor blockers to Angiotensin II receptor blockers (ARBs) and diuretics. • Revised the term capsule in the manufacturing outlines to tablet. • Had applied for film-coated tablet without providing coating composition and process. The firm was asked to provide proof of international availability in the reference regulatory agencies as defined by the registration board in its 275th meeting, or revise the formulation to uncoated tablet. The firm did not comply. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also submit revised form 5, its annexures and label claim as uncoated tablets as per reference product and submission of pre-registration variation fee.**	
108.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Savantazide Tablet 32mg/25mg
	Composition	Each Film Coated Tablet Contains: Candesartan Cilexetil……..…32mg Hydrochlorothiazide……..…25mg
	Diary No. Date of R& I & fee	Dy. No. 12277 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	2x14's,; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan and Hydrochlorothiazide 32 mg/25 mg Tablets, uncoated. MHRA approved
	Me-too status	Cansaar Forte Tablets (film-coated). Reg No. 39581
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator.	• Revised the pharmacological group from angiotensin receptor blockers to Angiotensin II receptor blockers (ARBs) and diuretics. • Revised the term capsule in the manufacturing outlines to tablet. • Had applied for film-coated tablet without providing coating composition and process. The firm was asked to provide proof of international availability in the reference regulatory agencies as defined by the registration board in its 275th meeting, or revise the formulation to uncoated tablet. The firm did not comply. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.

	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also submit revised form 5, its annexures and label claim as uncoated tablets as per reference product and submission of pre-registration variation fee.**	
109.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Tranic Injection 1gm/5ml
	Composition	Each 5ml Contains: Tranexamic Acid…1g
	Diary No. Date of R& I & fee	Dy. No. 12261 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antihaemorrhagic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications. available in BP and JP
	Pack size & Demanded Price	1x10's (5ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Trasolide Injection 1gm/5ml. Reg No. 68820
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator.	• There was no initial sterilization of the ampules and terminal sterilization in the manufacturing outlines. The frim revised it. • Added filling, sealing and packing process in the manufacturing outlines. • Mentioned the oral route of administration. Then, revised it. • Submitted Rs. 7500/- fee (challan-07880832) • Proof of international availability of same formulation and same strength with filled volume of 5ml in reference regulatory authorities as defined in 275th meeting of the registration board is required
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
110.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Tranic Injection 500mg/5ml
	Composition	Each 5ml Contains: Tranexamic Acid…500mg
	Diary No. Date of R& I & fee	Dy. No. 12260 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antihaemorrhagic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications. available in BP and JP
	Pack size & Demanded Price	1x10's (5ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tranexamic acid 100mg/ml Solution for Injection (5ml, 10ml). MHRA approved
	Me-too status	Dravix 500mg/5ml Injection. Reg No. 76447
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator.	• There was no initial sterilization of the ampules and terminal sterilization in the manufacturing outlines. The frim revised it. • Added filling, sealing and packing process in the manufacturing outlines.

		• Mentioned the oral route of administration. Then, revised it. • Submitted Rs. 7500/- fee (challan-0663624757)
	Decision: Approved with BP specifications.	
111.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lansodex 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Enteric Coated Pellets Eq To Dexlansoprazole ……30mg
	Diary No. Date of R& I & fee	Dy. No.11828 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dexilant capsule, delayed release. USFDA approved.
	Me-too status	
	GMP status	swngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been signed by the applicant, i.e., CEO. • You have mentioned the demanded price as per requirement of the importing country. Clarify. • Justify the addition of 3% overage in the composition. • Specify the capsule shell material and other excipients used in pellets in the master formula. • Provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit stability data of three batches conducted in Zone IV-A. • Submit latest GMP inspection report.
	Decision: Deferred for the following; • **Justify the addition of 3% overage in the composition.** • **Specify the capsule shell material and other excipients used in pellets in the master formula.** • **Provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. In case of imported pellets, differential fee shall also be submitted.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board.** • **Latest GMP certificate/last inspection report conducted within last three years.**	
112.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lansodex 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Enteric Coated Pellets Eq To Dexlansoprazole ……..…60mg
	Diary No. Date of R& I & fee	Dy. No.11826 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dexilant capsule, delayed release. USFDA approved.
	Me-too status	
	GMP status	swngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been signed by the applicant, i.e., CEO. • You have demanded the price as per SRO and have mentioned the demanded price as per requirement of the importing country. Clarify. • Justify the addition of 3% overage in the composition. • Specify the capsule shell material and other excipients used in pellets in the master formula. • Provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit stability data of three batches conducted in Zone IV-A. • Submit latest GMP inspection report.
	Decision: Deferred for the following; • **Justify the addition of 3% overage in the composition.** • **Specify the capsule shell material and other excipients used in pellets in the master formula.** • **Provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. In case of imported pellets, differential fee shall also be submitted.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board.** • **Latest GMP certificate/last inspection report conducted within last three years.**	
113.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Oxazol 600mg/300ml Infusion
	Composition	Each Vial Of 300ml Contains: Linezolid ……600mg
	Diary No. Date of R& I & fee	Dy. No.11825 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	other antibacterials
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	1 vial (300ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (Linezolid) Injection, for Intravenous Use 200mg/100ml, 600mg/300ml. USFDA approved ZYVOX® (Linezolid) Injection, for Intravenous Use 400mg/200ml,. discontinued in USFDA not for safety / efficacy reasons.
	Me-too status	Linzol Infusion 600mg. Reg No. 81999
	GMP status	swngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.

		• Form 5 has not been signed by the applicant, i.e., CEO. Signed Form submitted. • Revisde the pharmacological group from antibiotics to "other antibacterials". • Demanded the price as per SRO and have mentioned the demanded price as per requirement of the importing country. Revised the price as per SRO. • The firm removed 3% overage in the composition. • Submitted Rs. 10000 fee (challan-2336766029) detail of the product not provided.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
114.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Moxiwan 400mg/250ml Infusion
	Composition	Each Vial Contains: Moxifloxacin as HCl ……..…400mg
	Diary No. Date of R& I & fee	Dy. No.11823 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	1 vial (250ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Moxifloxacin 400 mg/250 ml solution for infusion. MHRA approved.
	Me-too status	X-Lox 400mg Infusion. Reg No. 76970
	GMP status	swngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been signed by the applicant, i.e., CEO. Signed Form submitted. • Demanded the price as per SRO and have mentioned the demanded price as per requirement of the importing country. Revised the price as per SRO. • The firm removed 3% overage in the composition. • Already adjusted the weight of API as per equivalency factor Revised Moxifloxacin as HCl to Moxifloxacin HCl in the master formula. • Submitted Rs. 10000 fee (challan-2616286785) detail of the product not provided
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
115.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Race 500mg/5ml IV Injection
	Composition	Each Ampoule Contains: Levetiracetam ……..…500mg
	Diary No. Date of R& I & fee	Dy. No.11827 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs. Available in USP
	Pack size & Demanded Price	1 ampule (5ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam Wockhardt 100mg/ml concentrate for solution for infusion. MHRA approved.
	Me-too status	Epicetam Injection 500mg Reg No. 78922
	GMP status	swngmp

	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been signed by the applicant, i.e., CEO. Signed Form submitted. • Demanded the price as per SRO and have mentioned the demanded price as per requirement of the importing country. Revised the price as per SRO. • The firm removed 3% overage in the composition. • Submitted Rs. 10000 fee (challan-74345098) detail of the product not provided
	Decision: Approved with USP specifications. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
116.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Moxafil Infusion 100mg/50ml
	Composition	Each Vial Contains: Fluconazole ……100mg
	Diary No. Date of R& I & fee	Dy. No.11824 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Triazole and tetrazole derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has mentioned NaCl in excipients and claimed in-house specs. Available in USP (as Fluconazole in dextrose, and Fluconazole in NaCl), BP (Fluconazole infusion is sterile solution), IP (as Fluconazole in Water for injections) and JP (an aqueous injection, pH specified separately when the drug is granted approval based on the Law)
	Pack size & Demanded Price	1 vial (50ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fluconazole 2mg/ml solution for infusion (with NaCl) (50ml. 100ml, 200ml) in LDPE bottles or polyolefine bags. MHRA approved.
	Me-too status	Cozil I.V Infusion (50ml). Reg No. 77581
	GMP status	swngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been signed by the applicant, i.e., CEO. Signed Form submitted. • Demanded the price as per SRO and have mentioned the demanded price as per requirement of the importing country. Revised the price as per SRO. • The firm removed 3% overage in the composition. • Revised the pharmacological group from Triazole antifungal to Triazole and tetrazole derivatives. • Submitted Rs. 10000 fee (challan-34358762) detail of the product not provided
	Decision: Approved with USP specifications. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
117.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Sitamet 50/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate ……..…50mg Metformin HCl ……500mg
	Diary No. Date of R& I & fee	Dy. No.11809 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/500mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/500mg Tablets. Reg. No. 53099 (does not depict hydrate form).
	GMP status	swngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been signed by the applicant, i.e., CEO. Signed Form submitted. • Demanded the price as per SRO and have mentioned the demanded price as per requirement of the importing country. Revised the price as per SRO. • The firm removed 3% overage in the composition. • Revised the pharmacological group to Combinations of oral blood glucose lowering drugs. • Revised Sitagliptin Phosphate to Sitagliptin as phosphate monohydrate in the label claim and to Sitagliptin phosphate monohydrate in master formula and adjusted its weight in master formula as per equivalency factor. • Submitted Rs. 10000 fee (challan-98598893101) detail of the product not provided **Revised label claim is as under:** **Each Film Coated Tablet Contains:** **Sitagliptin as Phosphate monohydrate ..…50mg** **Metformin HCl ……500mg**
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of submission of 20,000/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
118.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Sitamet DS 50/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy. No.11820 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/1000mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/1000mg Tablets. Reg. No. 53100 (does not depict hydrate form).
	GMP status	swngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been signed by the applicant, i.e., CEO. Signed Form submitted. • Demanded the price as per SRO and have mentioned the demanded price as per requirement of the importing country. Revised the price as per SRO. • The firm removed 3% overage in the composition.

		• Revised the pharmacological group to Combinations of oral blood glucose lowering drugs. • Revised Sitagliptin Phosphate to Sitagliptin as phosphate monohydrate in the label claim and to Sitagliptin phosphate monohydrate in master formula and adjusted its weight in master formula as per equivalency factor. • Submitted Rs. 10000 fee (challan-5712486211) detail of the product not provided **Revised label claim is as under:** **Each Film Coated Tablet Contains:** **Sitagliptin as Phosphate monohydrate ..…50mg** **Metformin HCl ……1000mg**
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 20,000/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
119.	Name and address of manufacturer / Applicant	M/s Swan Pharmaceuticals Pvt Ltd 11-E, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tamisol 0.4mg Capsule
	Composition	Each Capsule Contains: Tamsulosin HCl Modified Release Pellets Eq. To Tamsulosin……..…0.4mg
	Diary No. Date of R& I & fee	Dy. No.11820 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use. **USFDA** approved
	Me-too status	Tamsolin 0.4mg Capsule. Reg. No. 50392
	GMP status	swngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been signed by the applicant, i.e., CEO. Signed Form submitted. • Demanded the price as per SRO and have mentioned the demanded price as per requirement of the importing country. Revised the price as per SRO. • The firm removed 5% overage in the composition. • Revised the pharmacological group from selective apha-1 blockers to Alpha-adrenoreceptor antagonists • The firm was asked to provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. The firm submitted the source as M/s vision pharmaceutical, Islamabad. • You have adjusted the weight of pellets as per strength of the pellets. Revise the weight considering the equivalency factor as well, because the pellets assay is in terms of Tamsulosin HCl. • The firm was asked to specify the capsule shell material. Specified as gelatin. • Submitted Rs. 10000 fee (challan-007366767153) detail of the product not provided

	Decision: Approved with BP specifications. Registration letter will be issued after submission of revised master formula with adjusting the weight of pellets as per strength of the pellets. Also revise the weight considering the equivalency factor as well, because the pellets assay is in terms of Tamsulosin HCl. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
120.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Leveron Oral Solution 100mg/ml
	Composition	Each ml Contains: Levetiracetam ……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 12257 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs. available in USP
	Pack size & Demanded Price	30ml, 60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	KEPPRA (levetiracetam) oral solution 100mg/ml. USFDA approved
	Me-too status	Evic Solution 100mg/ml. Reg. No. 82629
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Claimed levetricetam 100mg per ml. while it is levetricetam 100mg per 5ml in the master formula. Revised it to 100mg per ml. • Added filling and packing process in the manufacturing outlines.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of 20,000/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
121.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Savantazide Tablet 32mg/12.5mg
	Composition	Each Film Coated Tablet Contains: Candesartan Cilexetil ……..…32mg Hydrochlorothiazide ……..…12.5mg
	Diary No. Date of R& I & fee	Dy. No. 12258 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs. available in USP
	Pack size & Demanded Price	2x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan/Hydrochlorothiazide 32 mg/12.5 mg tablets. MHRA approved
	Me-too status	Advantec Tablet 32/12.5mg. Reg. No. 80270
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The firm was asked to revise the pharmacological group from Angiotensin II receptor antagonist to Angiotensin II receptor blockers (ARBs) and diuretics. The firm did not comply. • Revised the term capsule in the manufacturing outlines to tablet. • Added blistering and packing process in themanufacturing outlines.

		• Applied for film-coated tablet. Revised the formulation to uncoated tablet. • Submitted Rs. 7500 fee (challan-618788457) **Revised label claim is as under:** **Each Tablet Contains:** **Candesartan Cilexetil ……..…32mg** **Hydrochlorothiazide ……..…12.5mg**
	Decision: Approved with USP specifications. Registration letter will be issued after revision of the pharmacological group from Angiotensin II receptor antagonist to Angiotensin II receptor blockers (ARBs) and diuretics. • **Firm will also submit revised form 5, its annexures and label claim as uncoated tablets as per reference product and submission of pre-registration variation fee.**	
122.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	S Vant 32mg Tablet
	Composition	Each Film Coated Tablet Contains: Candesartan Cilexetil ……..…32mg
	Diary No. Date of R& I & fee	Dy. No. 12274 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II receptor blockers
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	2x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan 32 mg tablets. MHRA approved
	Me-too status	Skygen Neo Tablet. Reg. No. 67268
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from Angiotensin II receptor antagonist to Angiotensin II receptor blockers (ARBs). • Revised the term capsule in the manufacturing outlines to tablet. • Added blistering and packing process in the manufacturing outlines. • Applied for film-coated tablet without providing coating composition and process. Revised the formulation to uncoated tablet. • Submitted Rs. 7500 fee (challan-227562348726) **Revised label claim is as under:** **Each Tablet Contains:** **Candesartan Cilexetil ……..…32mg**
	Decision: Approved.	
123.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Riloxban Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban ……10mg
	Diary No. Date of R& I & fee	Dy. No. 12270 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Direct factor Xa inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs. Not available in USP
	Pack size & Demanded Price	2x10's, 5x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 10 mg film-coated tablets by Milpharm Limited. MHRA approved
	Me-too status	Xaroban 10mg Tablet. Reg. No. 76284
	GMP status	GMP certificate issued on 13.08.2022

	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from sedative & hypnotics to Direct factor Xa inhibitors. • Revised the term capsule in the manufacturing outlines to tablet. • Applied for film-coated tablet. Revised the composition and manufacturing outlines for film-coated tablet. • Submitted Rs. 7500 fee (challan-8090061729)
	Decision: Approved with BP specifications.	
124.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Riloxban Tablet 15mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban……..…15mg
	Diary No. Date of R& I & fee	Dy. No. 12271 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Direct factor Xa inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs. Not available in USP
	Pack size & Demanded Price	2x10's, 5x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 15 mg film-coated tablets by Milpharm Limited. MHRA approved
	Me-too status	Roxaban 15mg Tablet. Reg. No. 85165
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from sedative & hypnotics to Direct factor Xa inhibitors. • Revised the term capsule in the manufacturing outlines to tablet. • Applied for film-coated tablet. Revised the composition and manufacturing outlines for film-coated tablet. • Submitted Rs. 7500 fee (challan-6260071376)
	Decision: Approved with BP specifications.	
125.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Riloxban Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 12272 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Direct factor Xa inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs. Not available in USP
	Pack size & Demanded Price	2x10's, 5x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 20 mg film-coated tablets by Milpharm Limited. MHRA approved
	Me-too status	Roxaban 20mg Tablet. Reg. No. 85164
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from sedative & hypnotics to Direct factor Xa inhibitors. • Revised the term capsule in the manufacturing outlines to tablet.

		• Applied for film-coated tablet. Revised the composition and manufacturing outlines for film-coated tablet. • Submitted Rs. 7500 fee (challan-5365341204)
	Decision: Approved with BP specifications.	
126.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lorex plus 5/120mg Tablet
	Composition	Each Film Coated Tablet Contains: Loratadine……..……..…5mg Pseudoephadrine……120mg
	Diary No. Date of R& I & fee	Dy. No. 12278 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	other antihistamines for systemic use with sympathomimetics.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator. Decision:	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from antihistamines to antihistamines, sympathomimetics. • Applied for film coated tablet, added coating excipients and coating process in composition and manufacturing outlines. • Submitted fee Rs. 7500 (challan-8422359415) • Provide proof of international availability in the reference regulatory agencies as defined by the registration board in its 275th meeting. • Proof of me-too product (name and registration number) already approved by DRAP is required.
	Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
127.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Tranic 250mg Capsule
	Composition	Each Capsule Contains: Tranexamic Acid ……..…250mg
	Diary No. Date of R& I & fee	Dy. No. 12262 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antihemorrhagics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs. available in JP
	Pack size & Demanded Price	1x10's, 2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRANEX 250mg capsule. AIFA approved
	Me-too status	Tranza 250mg capsules. Reg No. 85769
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.

		• Specified the capsule shell material in the composition. • Revised the term tablet in the manufacturing outlines to capsule. • Removed the compression process from the manufacturing outlines. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with JP specifications. Registration letter will be issued after submission of 7500/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
128.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Tranic 500mg Capsule
	Composition	Each Capsule Contains: Tranexamic Acid…500mg
	Diary No. Date of R& I & fee	Dy. No. 12263 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antihemorrhagics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs. available in JP
	Pack size & Demanded Price	1x10's, 2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRANEX 500mg capsule. AIFA approved
	Me-too status	Sotran 500 Capsule. Reg No. 80350
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Specified the capsule shell material in the composition. • Revised the term tablet in the manufacturing outlines to capsule. • Removed the compression process from the manufacturing outlines. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with JP specifications. Registration letter will be issued after submission of 7500/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
129.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Tranic Injection 250mg/5ml
	Composition	Each 5ml Contains: Tranexamic Acid……..…250mg
	Diary No. Date of R& I & fee	Dy. No. 12259 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antihemorrhagics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs. available in BP and JP
	Pack size & Demanded Price	1x10's (5ml ampule); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Dravix 250mg/5ml Injection. Reg No. 76446
	GMP status	GMP certificate issued on 13.08.2022

	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Added initial sterilization of the ampules and terminal sterilization in the manufacturing outlines. Justify. • Added filling, sealing and packing process in the manufacturing outlines. • Mentioned the oral route of administration. Revised it to injectable. • Submitted fee Rs. 7500 (challan-29857311484) • Proof of international availability of same formulation and same strength with filled volume of 5ml in reference regulatory authorities as defined in 275th meeting of the registration board is required
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
130.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Linzox Infusion 200mg/100ml
	Composition	Each 100ml vial Contains: Linezolid ……..…200mg
	Diary No. Date of R& I & fee	Dy. No. 12266 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antibacterials
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	100ml vial; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (Linezolid) Injection, for Intravenous Use 200mg/100ml, 600mg/300ml. USFDA approved ZYVOX® (Linezolid) Injection, for Intravenous Use 400mg/200ml,. discontinued in USFDA not for safety / efficacy reasons.
	Me-too status	Linzol Infusion 200mg. Reg No. 81997
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from antibiotics to "antibacterials, oxazolidinone". • Applied for 200mg/100ml, while it is 200mg/5ml in the master formula. Revised it to 200mg/100ml. • Added initial sterilization of the vials and terminal sterilization in the manufacturing outlines. • Added filling, sealing and packing process in the manufacturing outlines. • Mentioned injection as the route of administration. Revised it to infusion. They did not mention IV route. • Submitted Rs. 7500 fee (challan-62653248765)
	Decision: Approved with innovator's specifications.	
131.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Linzox Infusion 400mg/200ml
	Composition	Each 200ml vial Contains: Linezolid ……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 12267 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	antibacterials, oxazolidinone

	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	200ml vial; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (Linezolid) Injection, for Intravenous Use 200mg/100ml, 600mg/300ml. USFDA approved ZYVOX® (Linezolid) Injection, for Intravenous Use 400mg/200ml,. discontinued in USFDA not for safety / efficacy reasons.
	Me-too status	Linzol Infusion 400mg. Reg No. 81998
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from antibiotics to "antibacterials, oxazolidinone". • Applied for 400mg/200ml, while it is 400mg/5ml in the master formula. Revised it to 400mg/200ml. • Added initial sterilization of the vials and terminal sterilization in the manufacturing outlines. • Added filling, sealing and packing process in the manufacturing outlines. • Mentioned injection as the route of administration. Revised it to infusion. They did not mention IV route. • Submitted Rs. 7500 fee (challan-260704160547)
	Decision: Approved with innovator's specifications.	
132.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Linzox Infusion 600mg/300ml
	Composition	Each 300ml vial Contains: Linezolid…600mg
	Diary No. Date of R& I & fee	Dy. No. 12268 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	antibacterials, oxazolidinone
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	300ml vial; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (Linezolid) Injection, for Intravenous Use 200mg/100ml, 600mg/300ml. USFDA approved ZYVOX® (Linezolid) Injection, for Intravenous Use 400mg/200ml,. discontinued in USFDA not for safety / efficacy reasons.
	Me-too status	Linzol Infusion 600mg. Reg No. 81999
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from antibiotics to "antibacterials, oxazolidinone". • Applied for 600mg/300ml, while it is 600mg/5ml in the master formula. Revised it to 600mg/300ml. • Added initial sterilization of the vials and terminal sterilization in the manufacturing outlines. • Added filling, sealing and packing process in the manufacturing outlines. • Mentioned injection as the route of administration. Revised it to infusion. They did not mention IV route. • Submitted Rs. 7500 fee (challan-81053039770)
	Decision: Approved with innovator's specifications.	

133.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Linzox Suspension 100mg/5ml
	Composition	Each 5ml Contains: Linezolid ……100mg
	Diary No. Date of R& I & fee	Dy. No. 12269 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	antibacterials, oxazolidinone
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX for Oral Suspension (granule/powder). USFDA approved
	Me-too status	Nezolid 100mg Suspension. Reg No. 50326
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from antibiotics to "antibacterials, oxazolidinone". • Applied for suspension, and have mentioned various liquids in the excipients. Moreover, the manufacturing outlines also depict that the product is liquid suspension. The reference product is dry suspension for reconstitution. Revised the applied product, the excipients and manufacturing outlines meant for dry suspension. • Added filling, sealing and packing process in the manufacturing outlines. • Submitted Rs. 7500 fee (challan-77194878506)
	Decision: Approved with innovator's specifications.	
134.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sericalm Suspension 2mg/ml
	Composition	Each ml Contains: Haloperidol Decanoate……..2mg
	Diary No. Date of R& I & fee	Dy. No. 12258 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Butyrophenone derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs. Available in USP and BP
	Pack size & Demanded Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Haloperidol Oral Solution BP 10mg/5 ml. MHRA approved Serenace 2mg/ml liquid solution. TGA approved (export only medicine).
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from tranquilizers to "Butyrophenone derivatives". • Applied for suspension, while you have mentioned syrup in the international reference. Revised oral suspension to oral solution. • Revised Haloperidol Decanoate…2mg to Haloperidol…2mg.

		• Add filling and packing process in the manufacturing outlines. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Proof of me-too product (name and registration number) already approved by DRAP is required.
	Decision: Deferred for following: • **Provide evidence of approval of applied formulation already approved by the Registration Board with brand name, manufacturer name & registration number or elsewise applied on the prescribed form i.e. Form 5D along with applicable fee.** • **Submission of stability data as per guidelines of 293rd meeting of Registration Board.** • **latest GMP certificate/last inspection report conducted within last three years.**	
135.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Montesafe Sachet 4mg
	Composition	Each Sachet Contains: Montelukast sodium ……..…4mg
	Diary No. Date of R& I & fee	Dy. No. 12271 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs. Available in USP
	Pack size & Demanded Price	1x28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SINGULAIR® (montelukast as sodium 4mg) oral granules. USFDA approved
	Me-too status	Inspra Oral Granules 4mg. Reg. No. 73781
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from bronchodialtor to "Leukotriene receptor antagonists". • Revised montelukast sodium to montelukast as sodium in the label claim only, and adjusted its weight as per salt factor in the master formula. • You have mentioned filled weight of 60ml in the manufacturing outlines. Clarify/ revise. • Submitted Rs. 75000 fee (challan-555769585188)
	Decision: Approved with USP specifications. Registration letter will be issued after submission of 22,500/- fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also revise their manufacturing outlines to remove 60ml fill volume and submission of pre-registration variation fee.**	
136.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zolcarb 20/1680 sachet
	Composition	Each Sachet Contains: Omeprazole ……..…20mg Sodium Bicarbonate ……..…1680mg
	Diary No. Date of R& I & fee	Dy. No. 12282 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole and sodium bicarbonate (Packet) for oral suspension. approved by US-FDA

	Me-too status	Risek Insta Sachet by Getz Pharma (Pvt.) Ltd., Karachi Reg. No. 58547
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Applied for omeprazole 20mg and sodium bicarbonate 1680mg sachet. • Later, submitted properly filled enclosure of Form 5. • Later, submitted undertaking at the end of form 5. • Later, submitted the exact label claim, composition with list of excipients and manufacturing outlines. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
137.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zolcarb forte 40/1680 sachet
	Composition	Each Sachet Contains: Omeprazole ……..…40mg Sodium Bicarbonate ……1680mg
	Diary No. Date of R& I & fee	Dy. No. 12283 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Proton pump inhibitor.
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole and sodium bicarbonate (Packet) for oral suspension. approved by US-FDA
	Me-too status	Risek Insta Sachet by Getz Pharma (Pvt.) Ltd., Karachi Reg. No. 58548
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Applied for omeprazole 40mg and sodium bicarbonate 1680mg sachet. • Later, submitted properly filled enclosure of Form 5. • Later, submitted undertaking at the end of form 5. • Later, submitted the exact label claim, composition with list of excipients and manufacturing outlines. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
138.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Awacol 11MU IV Injection
	Composition	Each Vial Contains: Colistimethate Sodium (Lyophilized Powder) ……1MIU
	Diary No. Date of R& I & fee	Dy. No.12455 dated 06.03.2019

		Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Antibiotic (polymyxin)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection (lyophilized powder in glass vial). Approved by **MHRA**
	Me-too status	Colistat powder for Injection. Reg. No. 76160
	GMP status	M/s Usawa Pharmaceuticals was inspected on 08.01.2019, wherein satisfactory level of GMP was reported M/s Usawa Pharmaceuticals was inspected on 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 wherein renewal of DML / regularization of layout plan, grant of additional section as well as change in section was recommended
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Did not provide chemical name of the API at serial No. 03. Later on, submitted it. • Had mentioned Colistimethate Sodium eq. to Colistimethate and mentioned its weight as 85.68mg in master formula. Then, mentioned Colistimethate Sodium…1MIU and revised 85.68mg to 90mg (for 7% water contents and 4%overage). Then, revised Colistimethate Sodium…90mg (for 7% water contents and 4%overage to Colistimethate Sodium…80mg. But the label claim in the revised documents is Colistimethate Sodium eq. to Colistimethate….1MIU. Then, once again submitted the label claim "Each Vial Contains: Colistimethate Sodium (Lyophilized Powder)…1MIU" shall be considered. • Also mentioned water for injection, and lyophilization process. • Added packing process to the manufacturing outlines. • Revised brand Awacol 11MU to Awacol 1MIU. • Submitted Rs. 7500 (challan- 557752858924)
	Decision: Registration Board deferred the case for submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.	
139.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Usven 500mg Injection
	Composition	Each Vial Contains: Vancomycin as HCl ……500mg
	Diary No. Date of R& I & fee	Dy. No.12456 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Tricyclic Glycopeptide
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	VANCOCIN CP vancomycin 500mg (as hydrochloride) powder for injection vial. TGA approved
	Me-too status	Vanzy 500mg Injection. Reg. No. 81901
	GMP status	M/s Usawa Pharmaceuticals was inspected on 08.01.2019, wherein satisfactory level of GMP was reported M/s Bio-lab was inspected on 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 wherein renewal of DML / regularization of layout plan, grant of additional section as well as change in section was recommended
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Had adjusted the weight of API as per salt factor in the master formula. Revised Vancomycin as HCl to Vancomycin HCl in the master formula. • Mentioned the excipients in the master formula/ composition. • Submitted complete manufacturing outlines. • Enclosure of Form 5 from point 16 onwards was missing. Submitted it. • Submitted Rs. 75000 (challan- 3626024049)
	Decision: Deferred for the following; • **Confirmation of manufacturing method for the applied formulation whether through lyophilization process or otherwise.** • **Latest GMP certificate/last inspection report conducted within last three years for contract acceptor.**	
140.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Usven 1g Injection
	Composition	Each Vial Contains: Vancomycin as HCl ……..…1g
	Diary No. Date of R& I & fee	Dy. No.12454 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Tricyclic Glycopeptide
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VANCOCIN CP vancomycin 1g (1,000,000IU as hydrochloride) powder for injection vial. TGA approved
	Me-too status	Vanzy 1g Injection. Reg. No. 81902
	GMP status	M/s Usawa Pharmaceuticals was inspected on 08.01.2019, wherein satisfactory level of GMP was reported M/s M/s Bio-lab was inspected on 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 wherein renewal of DML / regularization of layout plan, grant of additional section as well as change in section was recommended
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Had adjusted the weight of API as per salt factor in the master formula. Revised Vancomycin as HCl to Vancomycin HCl in the master formula.

		• Mentioned the excipients in the master formula/ composition. • Submitted Rs. 75000 (challan- 6159809290)
	Decision: Deferred for the following; • **Confirmation of manufacturing method for the applied formulation whether through lyophilization process or otherwise.** • **Latest GMP certificate/last inspection report conducted within last three years for contract acceptor.**	
141.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ketoride 30mg Ampoule
	Composition	Each Ampoule Contains: Ketorolac Tromethamine ……..…30mg
	Diary No. Date of R& I & fee	Dy. No.12453 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TORADOL ketorolac trometamol 30mg/1mL (ketorolac trometamol 30mg without equivalency) injection ampoule. TGA approved.
	Me-too status	Syntor 30 mg Injection IV/IM. Reg. No. 83365
	GMP status	M/s Usawa Pharmaceuticals was inspected on 08.01.2019, wherein satisfactory level of GMP was reported M/s M/s Bio-lab was inspected on 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 wherein renewal of DML / regularization of layout plan, grant of additional section as well as change in section was recommended
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Submitted complete manufacturing outlines. • Enclosure of Form 5 from point 16 onwards was missing. Submitted it. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board deferred the case for further deliberation regarding the sterilization method of the applied formulation whether by way of terminal sterilization or otherwise.	
142.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan By M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Dupagest Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Dydrogesterone ……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 13044 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Progestogen
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed BP specs.
	Pack size & Demanded Price	As per SRO; Rs 600/-
	Approval status of product in Reference Regulatory Authorities.	Duphaston 10 mg film-coated tablets. Approved in **Belgium**
	Me-too status	D-Gest 10mg Tablets. Reg. No. 77100
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The firm has claimed tran isomer of the drug substance. • The address of manufacturer in Form 5 is M/s Aries Pharmaceuticals, 1-W, Industrial Estate, Hayatabad, Peshawar, KPK, Pakistan, while it is M/s Aries Pharmaceuticals (Pvt.) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar in the DML.
		• Form 5 shall be submitted by the applicant, not manufacturer along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit copy of the DML of the applicant. • Submit undertaking at the end of Form 5. • Submit valid GMP inspection reports of both the firms.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of Form 5 by the applicant, not manufacturer along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • **Latest GMP certificate/last inspection report conducted within last three years of both the contact acceptor and giver shall be submitted.**	
143.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan By M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Estrop Tablet 2/2/0.5mg
	Composition	Each 11 White Sugar Coated Tablet Contains: Estradiol Valerate ……..…2mg Each 10 Light Brown Sugar Coated Tablet Contains: Estadiol Valerate ……..…2mg Norgestrel ……..…0.5mg
	Diary No. Date of R& I & fee	Dy. No. 13047 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Oestrogen agonist / Progestogen
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	21's; Rs 300/-
	Approval status of product in Reference Regulatory Authorities.	Cyclo-Progynova® 2mg Sugar-coated tablets. MHRA approved
	Me-too status	Nexate Tablets. Reg. No. 71222
	GMP status	High-Q: Copy of inspection report dated 10-8-2022 concludes good level of compliance Aries: cGMP certificate on the basis of Evaluation conducted on 06-04-2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address of manufacturer in Form 5 is M/s Aries Pharmaceuticals, 1-W, Industrial Estate,

		Hayatabad, Peshawar, KPK, Pakistan, while it is M/s Aries Pharmaceuticals (Pvt) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar in the DML.
		• Form 5 shall be submitted by the applicant, not manufacturer along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • You have submitted same coating process for both the brown and white tablets. Clarify. • Submit copy of the DML of the applicant. • Submit undertaking at the end of Form 5. • Submit valid GMP inspection reports of both the firms.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of Form 5 by the applicant, not manufacturer along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
144.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan By M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Noreta 2mg/35mcg Tablet
	Composition	Each Film Coated Tablet Contains: Cyproterone Acetate ……..…2mg Ethinylestradiol ……..…35mcg
	Diary No. Date of R& I & fee	Dy. No. 13045 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Anti-androgen / Oestrogen
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specs.
	Pack size & Demanded Price	21's; Rs 300/-
	Approval status of product in Reference Regulatory Authorities.	Co-cyprindiol 2000/35 Tablets film-coated. MHRA approved
	Me-too status	Acne-Heal Tablet. Reg. No. 73476
	GMP status	High-Q: Copy of inspection report dated 10-8-2022 concludes good level of compliance Aries: cGMP certificate on the basis of Evaluation conducted on 06-04-2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address of manufacturer in Form 5 is M/s Aries Pharmaceuticals, 1-W, Industrial Estate, Hayatabad, Peshawar, KPK, Pakistan, while it is M/s Aries Pharmaceuticals (Pvt) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar in the DML.
		• Form 5 shall be submitted by the applicant, not manufacturer along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit copy of the DML of the applicant. • Submit undertaking at the end of Form 5. • Submit valid GMP inspection reports of both the firms.

	Decision: Approved. Registration letter will be issued after submission of Form 5 by the applicant, not manufacturer along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
145.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan By M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Primela Tablet 5mg
	Composition	Each Tablet Contains: Norethisterone ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 13046 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Progestogen
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specs.
	Pack size & Demanded Price	As per SRO; Rs 200/-
	Approval status of product in Reference Regulatory Authorities.	Norethisterone 5mg Tablets, uncoated. MHRA approved
	Me-too status	Postpon-M Tablet 5mg. 73532
	GMP status	High-Q: Copy of inspection report dated 10-8-2022 concludes good level of compliance Aries: cGMP certificate on the basis of Evaluation conducted on 06-04-2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. The address of manufacturer in Form 5 is M/s Aries Pharmaceuticals, 1-W, Industrial Estate, Hayatabad, Peshawar, KPK, Pakistan, while it is M/s Aries Pharmaceuticals (Pvt) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar in the DML.
		• Form 5 shall be submitted by the applicant, not manufacturer along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit copy of the DML of the applicant. • Submit undertaking at the end of Form 5. • Submit valid GMP inspection reports of both the firms.
	Decision: Approved. Registration letter will be issued after submission of Form 5 by the applicant, not manufacturer along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
146.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Aprent Capsules 80mg
	Composition	Each Hard Gelatin Capsule Contains: Aprepitant ……..…80mg
	Diary No. Date of R& I & fee	Dy. No. 11716 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antimetic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Emend 80mg hard capsules. USFDA approved.

	Me-too status	Apritus 80mg Capsule. Reg. No. 74886
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
147.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Artho K Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Diclofenac Potassium ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 11732 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diclofenac Potassium 50 mg Tablets, film-coated. MHRA approved
	Me-too status	Arnil-P 50mg Tablet. Reg. No. 82129
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • You have mentioned the quantity of API as 55.85mg per tablet. Revise the composition / master formula as per label claim. • Submit fee for above revisions as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	

148.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Erycin Tablet 250mg
	Composition	Each Film Coated Tablet Contains: Erythromycin stearate eq. to erythromycin …….250mg
	Diary No. Date of R& I & fee	Dy. No. 11723 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Macrolide group of antibiotics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 20's, 30's, 100's, 500's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Erythromycin 250mg film-coated tablets. MHRA approved
	Me-too status	Erobicin 250mg Tablet. Reg. No. 73812
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Submit fee for above revisions as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
149.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Erycin Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Erythromycin stearate eq to erythrmycin…500mg
	Diary No. Date of R& I & fee	Dy. No. 11709 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Macrolide group of antibiotics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 20's, 30's, 100's, 500's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Erythromycin 500mg film-coated tablets. MHRA approved
	Me-too status	Erobicin 500mg Tablet. Reg. No. 73813
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad,

		Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Submit fee for above revisions as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
150.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Bet Tablet 150mg
	Composition	Each Film Coated Tablet Contains: Irbesartan ……150mg
	Diary No. Date of R& I & fee	Dy. No. 11713 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II Receptor Blockers (ARBs), Plain.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specs.
	Pack size & Demanded Price	10's, 20's, 30's, 60's,; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Irbesartan 150 mg film-coated tablets. MHRA approved
	Me-too status	Arbista 150mg Tablet. Reg. No. 83013
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Submit fee for above revisions as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
151.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Lamid 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide ……..…150mg
	Diary No. Date of R& I & fee	Dy. No. 11712 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Funcitional aminoacid
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.

	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Accord 150 mg film-coated tablets. MHRA approved.
	Me-too status	Lacolep 150mg Tablet . Reg. No. 73859
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Revise the pharmacological group.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021** • **Correction of pharmacological group**	
152.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Lamid 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide ……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 11711 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Funcitional aminoacid
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Accord 100 mg film-coated tablets. MHRA approved.
	Me-too status	Lacolep 100mg Tablet . Reg. No. 73858
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Revise the pharmacological group.
	Decision: Deferred for following:	

	• **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct pharmacological group of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021** • **Correction of pharmacological group**	
153.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Lamid 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 11710 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Funcitional aminoacid
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Accord 50 mg film-coated tablets. MHRA approved.
	Me-too status	Lacolep 50mg Tablet . Reg. No. 73857
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Revise the pharmacological group.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct pharmacological group of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021** • **Correction of pharmacological group**	
154.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Zapine Tablet 30mg
	Composition	Each Film Coated Tablet Contains: Mirtazapine ……..…30mg
	Diary No. Date of R& I & fee	Dy. No. 11730 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mirtazapine 30mg tablets. MHRA Approved
	Me-too status	Jeta 30mg Tablets. Reg. No. 77035

	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Revise the pharmacological group.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct pharmacological group of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
155.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Zapine Tablet 15mg
	Composition	Each Film Coated Tablet Contains: Mirtazapine ……..…15mg
	Diary No. Date of R& I & fee	Dy. No. 11729 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mirtazapine 15mg tablets. MHRA Approved
	Me-too status	Jeta 15mg Tablets. Reg. No. 77034
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Revise the pharmacological group.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct pharmacological group of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	

156.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Roxet Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Paroxetine as HCl ……20mg
	Diary No. Date of R& I & fee	Dy. No. 11724 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	SSRI
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paroxetine 20mg Film-coated Tablets (as hydrochloride anhydrous). MHRA Approved
	Me-too status	P-OX 20mg Tablets. Reg. No. 78013
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Revise Paroxetine as HCl to Paroxetine HCl in the master formula only.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct pharmacological group of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
157.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Roxet CR Tablet 25mg
	Composition	Each Control Release Tablet Contains: Paroxetine as HCl ……..…25mg
	Diary No. Date of R& I & fee	Dy. No. 11733 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	SSRI
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paxil CR Tablet 25mg. USFDA approved.
	Me-too status	Impika CR Tablet. Reg. No. 84447
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file.

		• The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Revise Paroxetine as HCl to Paroxetine HCl in the master formula only. • You have submitted the reference wherein it is stated that: ➢ Each extended-release tablet contains 12.5 mg, 25 mg, or 37.5 mg paroxetine equivalent to 14.25 mg, 28.51 mg, or 42.76 mg of paroxetine hydrochloride, respectively. The factor used is meant for hemihydrate form. ➢ One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix. ➢ In addition to controlling the rate of drug release in vivo, an enteric coat delays the start of drug release until tablets of PAXIL CR have left the stomach. Revise your composition, master formula, and manufacturing method in line with the above-mentioned facts. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct label claim as per innovator product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
158.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Roxet CR Tablet 37.5mg
	Composition	Each Control Release Tablet Contains: Paroxetine As HCl ……..…37.5mg
	Diary No. Date of R& I & fee	Dy. No. 11740 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	SSRI
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paxil CR Tablet 37.5mg. USFDA approved.
	Me-too status	Peroxa CR 37.5 mg Tablet. Reg. No. 82118
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt)

		Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Revise Paroxetine as HCl to Paroxetine HCl in the master formula only. • You have submitted the reference wherein it is stated that: ➢ Each extended-release tablet contains 12.5 mg, 25 mg, or 37.5 mg paroxetine equivalent to 14.25 mg, 28.51 mg, or 42.76 mg of paroxetine hydrochloride, respectively. The factor used is meant for hemihydrate form. ➢ One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix. ➢ In addition to controlling the rate of drug release in vivo, an enteric coat delays the start of drug release until tablets of PAXIL CR have left the stomach. Revise the composition, master formula, and manufacturing method in line with the above-mentioned facts. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct label claim as per innovator product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
159.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Pine XR Tablet 300mg
	Composition	Each Extended Release Tablet Contains: Quetiapine as fumarate ……300mg
	Diary No. Date of R& I & fee	Dy. No. 11735 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	atypical antipsychotic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL® XR (quetiapine fumarate) 300mg tablets. USFDA approved
	Me-too status	Angepine XR Tablets . Reg. No. 78826
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it.

		• You have mentioned the weight of API as 345mg/tablet. Revise it as per salt factor. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
160.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Pin Tablet 1mg
	Composition	Each Film Coated Tablet Contains: Ropinirole HCl ……1mg
	Diary No. Date of R& I & fee	Dy. No. 11727 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Dopamine agonist
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 21's, 28's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ropinirole 1 mg film-coated tablets (as hydrochloride) 1mg. MHRA approved.
	Me-too status	Zeque Tablets 1mg. 52636
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Revise ropinirole as HCl to ropinirole HCl in the master formula only. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Revise the pharmacological group to dopamine agonists.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct pharmacological group of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
161.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Pin Tablet 2mg
	Composition	Each Film Coated Tablet Contains: Ropinirole HCl ……2mg
	Diary No. Date of R& I & fee	Dy. No. 11728 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Dopamine agonist

	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 21's, 28's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ropinirole 2 mg film-coated tablets (as hydrochloride) 1mg. MHRA approved.
	Me-too status	Zeque Tablets 2mg. 52637
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Revise ropinirole as HCl to ropinirole HCl in the master formula only. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Revise the pharmacological group to dopamine agonists.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline and correct pharmacological group of applied product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
162.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	A Sart Tablet 80mg/5mg
	Composition	Each Tablet Contains: Telmisartan ……80mg Amlodipine as besylate ……5mg
	Diary No. Date of R& I & fee	Dy. No. 11719 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II antagonists and dihydropyridine calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (5/80mg). TGA approved
	Me-too status	Ezitab-AM Tablet. Reg. No. 082044
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".

		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Revise amlodipine as besylate to amlodipine besylate in the master formula only. • You have mentioned the weight of besylate to amlodipine 7mg/tablet. Reivse it as per salt factor. • The reference product in USFDA and TGA is bilayer tablet. You have applied for plain / single layer tablet. Justifications is required. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product for bilayer tablet with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Evidence of availability of bilayer compression machine shall also be submitted.**	
163.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	A Sart Tablet 80mg/10mg
	Composition	Each Tablet Contains: Telmisartan ……..…80mg Amlodipine as besylate ……10mg
	Diary No. Date of R& I & fee	Dy. No. 11720 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II antagonists and dihydropyridine calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (10/80mg). TGA approved
	Me-too status	AM-Telsan 10/ 80 tablet. Reg. Np. 67434
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Revise amlodipine as besylate to amlodipine besylate in the master formula only. • You have mentioned the weight of besylate to amlodipine 14mg/tablet. Reivse it as per salt factor. • The reference product in USFDA and TGA is bilayer tablet. You have applied for plain / single layer tablet. Justifications is required. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following:	

	• **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product for bilayer tablet with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Evidence of availability of bilayer compression machine shall also be submitted.**	
164.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	A Sart Tablet 40mg/5mg
	Composition	Each Tablet Contains: Telmisartan ……..…40mg Amlodipine as besylate ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 11717 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Angiotensin II antagonists and dihydropyridine calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (5/40mg). TGA approved
	Me-too status	Ezitab-AM Tablet. Reg. No. 082041
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Revise amlodipine as besylate to amlodipine besylate in the master formula only. • You have mentioned the weight of besylate to amlodipine 7mg/tablet. Reivse it as per salt factor. • The reference product in USFDA and TGA is bilayer tablet. You have applied for plain / single layer tablet. Justifications is required. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product for bilayer tablet with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Evidence of availability of bilayer compression machine shall also be submitted.**	
165.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	A Sart Tablet 40mg/10mg
	Composition	Each Tablet Contains: Telmisartan ……..…40mg Amlodipine as besylate ……10mg
	Diary No. Date of R& I & fee	Dy. No. 11718 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019

	Pharmacological Group	Angiotensin II antagonists and dihydropyridine calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (10/40mg). TGA approved
	Me-too status	Ezitab-AM Tablet. Reg. No. 082045
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan" while it is "Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• You have submitted the manufacturing method mentioning granules and tubes; revise it. • Revise amlodipine as besylate to amlodipine besylate in the master formula only. • You have mentioned the weight of besylate to amlodipine 14mg/tablet. Reivse it as per salt factor. • The reference product in USFDA and TGA is bilayer tablet. You have applied for plain / single layer tablet. Justifications is required. • For above revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product for bilayer tablet with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Evidence of availability of bilayer compression machine shall also be submitted.**	
166.	Name and address of manufacturer / Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 05, Street No. S-05, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Zomid Capsules 100mg
	Composition	Each Hard Gelatin Capsule Contains: Zonisamide ……100mg
	Diary No. Date of R& I & fee	Dy. No. 11722 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZONEGRAN® (zonisamide) capsules 100mg. Approved in USFDA.
	Me-too status	Zonisa 100mg Capsule. Reg. No. 58505
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Stamped signatures of the QCM and PM are placed in the file. • The firm mentioned the address as "M/s Goodman Laboratories. No.5, Street No. S-5, National

		Industrial Zone, Rawat, Rawalpindi" while it is "M/s Goodman Laboratories. (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad".
		• The reference product in USFDA contains hydrogenated vegetable oil (from soyabean) and sodium laurilsulfate. Justification is required for not mentioning the same in the applied product. • You have submitted the composition / master formula for fenofibrate; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • You have submitted the manufacturing method mentioning granules and tubes; revise it along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product as per innovator product with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**	
167.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Moximox 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Moxifloxacin as HCl ……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 13067 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Quinolone antibiotics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Moxifloxacin 400 mg film-coated tablets. Approved in MHRA.
	Me-too status	Navilox 400mg Tablet. Reg. No. 85166
	GMP status	Firm has submitted copy of GMP certificate dated 04-01-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 has not been submitted. • Submit copy of the DML. • The reference product in MHRA contains Moxifloxacin HCl…400mg, you have applied for Moxifloxacin as HCl…400mg. Revise the label claim, and quantity of API in the master formula without equivalency along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of 7500/- fee for pre-approval changes/correction in the specifications as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
168.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tacrim Capsule 0.5mg
	Composition	Each Capsule Contains: Tacrolimus ……..…0.5mg
	Diary No. Date of R& I & fee	Dy. No. 12755 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019

	Pharmacological Group	Immunosuppresant
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROGRAF 0.5mg, 1mg, 5mg capsule. **USFDA** approved
	Me-too status	Tacgraf Capsule 0.5mg. Reg. No. 68114
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • Revise the pharmacological group to Calcineurin inhibitors. • In USFDA, PROGRAF is available for oral administration as capsules (tacrolimus capsules USP) containing the equivalent of 0.5 mg, 1 mg or 5 mg of anhydrous tacrolimus USP Revise tacrolimus to tacrolimus monohydrate in the master formula and adjust its weight in master formula based on salt factor • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved.	
169.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tacrim Capsule 5mg
	Composition	Each Capsule Contains: Tacrolimus ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 12756 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROGRAF 0.5mg, 1mg, 5mg capsule. **USFDA** approved
	Me-too status	Tacgraf Capsule 5mg. Reg. No. 68116
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • Revise the pharmacological group to Calcineurin inhibitors. • In USFDA, PROGRAF is available for oral administration as capsules (tacrolimus capsules USP) containing the equivalent of 0.5 mg, 1 mg or 5 mg of anhydrous tacrolimus USP Revise tacrolimus to tacrolimus monohydrate in the master formula and adjust its weight in master formula based on salt factor

		• For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved.	
170.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tazomil Cream 0.1% w/w
	Composition	Each Gram of Cream Contains: Tazarotene ……..…1mg
	Diary No. Date of R& I & fee	Dy. No. 12745 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsoriasis
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	5g, 10g, 15g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVAGE ® (tazarotene) cream, 0.1%, for topical use. **USFDA** approved
	Me-too status	Taz 0.1% cream. Reg. No. 81185
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add packing process to the manufacturing outlines. • Revise the pharmacological group to Other antipsoriatics for topical use. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for pre-approval changes/correction in the specifications as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
171.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tazomil Gel 0.1% w/w
	Composition	Each Gram of gel Contains: Tazarotene ……..…1mg
	Diary No. Date of R& I & fee	Dy. No. 12744 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsoriasis
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	5g, 10g, 15g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZORAC 0.1%, gel. **MHRA** approved
	Me-too status	Trazene 0.1% Gel. Reg. No. 57747
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• You have added emulsifying agent in the gel. Calrify. • You have added any gelling agent to the gel composition. Clarify. • Add packing process to the manufacturing outlines.

		• Revise the pharmacological group to Other antipsoriatics for topical use. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for pre-approval changes/correction in the specifications as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
172.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	TM Soliten Tablet 0.4/6mg
	Composition	Each Film Coated Tablet Contains: Tamsulosin HCl……..…0.4mg Solifenacin Succinate……..…6mg
	Diary No. Date of R& I & fee	Dy. No. 12735 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vesomni 6 mg/0.4 mg modified release film-coated tablets (bilayer). MHRA approved. Vesomni 6 mg/0.4 mg is a modified-release tablet composed of one layer containing 6 mg solifenacin succinate (immediate release) and a second layer containing 0.4 mg tamsulosin hydrochloride (Oral Controlled Absorption System/modified release)
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The reference product contains modified release pellets of solifenacin succinate. Revise the label claim, composition and manufacturing outlines. • Add blistering and packing process to the manufacturing outlines. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit stability data as per zone IV-A.
	Decision: Deferred for the following: • **The reference product contains modified release pellets of solifenacin succinate. Revise the label claim, composition and manufacturing outlines as per reference product with applicable fee.** • **Provide evidence of approval of applied formulation already approved by the Registration Board with brand name & registration number or elsewise applied on the prescribed form i.e. Form 5D along with applicable fee.** • **Submission of stability data as per guidelines of 293rd meeting of Registration Board.** • **Add blistering and packing process to the manufacturing outlines.**	
173.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Biscord H Tablet 10/6.25mg
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate ……..…10mg Hydrochlorothiazide ……..…6.25mg

	Diary No. Date of R& I & fee	Dy. No. 12733 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's;, 14's, 20's, 28's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZIAC® (Bisoprolol Fumarate and Hydrochlorothiazide) Tablets10/6.25mg. **USFDA** approved
	Me-too status	Valvozid-10 Plus Tablets.. Reg. No. 47718
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • Revise the Pharmacological group. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved. Registration letter will be issued after submission revised manufacturing outlines, revised pharmacological group with 7500/- fee for pre-approval changes/correction in the specifications as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
174.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ecrim Tablet 0.25mg
	Composition	Each Tablet Contains: Everolimus ……..…0.25mg
	Diary No. Date of R& I & fee	Dy. No. 12773 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Mammalian target of rapamycin (mTOR) kinase inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Certican 0.25 mg tablets, uncoated. MHRA approved.
	Me-too status	Afitor 0.25mg tablet of M/s Safe Pharma
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit proof of me-too product (name and registration number) already registered by DRAP.
	• **Decision: Approved with Innovator's specifications against the available section of "Tablet (Anti-cancer"). The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
175.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore

	Brand Name +Dosage Form + Strength	Ecrim Tablet 0.75mg
	Composition	Each Tablet Contains: Everolimus ……..…0.75mg
	Diary No. Date of R& I & fee	Dy. No. 12774 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Mammalian target of rapamycin (mTOR) kinase inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zortress tablets for oral administration 0.25 mg, 0.5 mg, and 0.75 mg. USFDA approved.
	Me-too status	Primus 0.75mg tablet of M/s Rotex Pharma Reg.# 101693
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit proof of me-too product (name and registration number) already registered by DRAP.
	• **Decision: Approved with Innovator's specifications against the available section of "Tablet (Anti-cancer"). The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
176.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ecrim Tablet 5mg
	Composition	Each Tablet Contains: Everolimus ……5mg
	Diary No. Date of R& I & fee	Dy. No. 12775 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Mammalian target of rapamycin (mTOR) kinase inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AFINITOR® (everolimus) tablets, for oral use 2.5 mg, 5 mg, 7.5 mg, or 10 mg. USFDA approved.
	Me-too status	AFINITOR 5MG TABLETS. Reg. No. 69519
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with Innovator's specifications against the available section of "Tablet (Anti-cancer"). The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

177.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ecrim Tablet 10mg
	Composition	Each Tablet Contains: Everolimus ……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 12776 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Mammalian target of rapamycin (mTOR) kinase inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AFINITOR® (everolimus) tablets, for oral use 2.5 mg, 5 mg, 7.5 mg, or 10 mg. USFDA approved.
	Me-too status	AFINITOR 10MG TABLETS. Reg. No. 69520
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with Innovator's specifications against the available section of "Tablet (Anti-cancer"). The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
178.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Roxonib Tablet 20mg
	Composition	Each Tablet Contains: Ruxolitinib As Phosphate ……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 12770 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Janus-associated kinase (JAK) inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	10's, 20's, 56's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JAKAFI® (ruxolitinib) uncoated tablets, for oral use 5 mg, 10 mg, 15 mg, 20 mg. USFDA approved.
	Me-too status	JAKAVI 20MG TABLETS. Reg. No. 78121 (does not depict the salt form)
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • You have adjusted the weight of API as per salt factor; revise Ruxolitinib As Phospate to Ruxolitinib Phospate in the master formula. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.

	Decision: Approved with Innovator's specifications against the available section of "Tablet (Anti-cancer"). The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
179.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Vortix Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Vortioxetine Hydro bromide Eq. To Vortioxetine ……10mg
	Diary No. Date of R& I & fee	Dy. No. 12747 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	SSRIs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JAKAFI® (ruxolitinib) uncoated tablets, for oral use 5 mg, 10 mg, 15 mg, 20 mg. USFDA approved.
	Me-too status	JAKAVI 20MG TABLET. Reg. No. 78121 (does not depict the salt form)
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • You have adjusted the weight of API as per salt factor; revise Vortioxetine as Hydrobromide to Vortioxetine Hydrobromide in the master formula. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit stability data as per zone IV-A.
	Decision: Deferred for the followings; • **Add blistering and packing process to the manufacturing outlines.** • **You have adjusted the weight of API as per salt factor; revise Vortioxetine as Hydro bromide to Vortioxetine Hydro bromide in the master formula.** • **For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Stability study data as per guidelines approved in 293rd meeting of Registration Board.**	
180.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tamodex Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Tamoxifen as Citrate ……10mg
	Diary No. Date of R& I & fee	Dy. No. 12757 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specs.
	Pack size & Demanded Price	20's, 30's, 60's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TAMOXIFEN SANDOZ tamoxifen 10mg and 20mg (as citrate) tablet film-coated. USFDA approved.
	Me-too status	TAMOXIFEN-SANDOZ 10MG TABLETS. Reg. No. 47670 (does not depict the salt form)
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-

		2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • You have adjusted the weight of API as per salt factor; revise Tamoxifen as Citrate to Tamoxifen Citrate in the master formula. • Revise the pharmacological group to Anti-estrogens. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved. Registration letter will be issued after submission of revised manufacturing outline with addition of blistering and packing process, revised pharmacological group to Anti-estrogens along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
181.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tamodex Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Tamoxifen as Citrate ……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 12758 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specs.
	Pack size & Demanded Price	20's, 30's, 60's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TAMOXIFEN SANDOZ tamoxifen 10mg and 20mg (as citrate) tablet film-coated. USFDA approved.
	Me-too status	TAMOXIFEN-SANDOZ 20MG TABLETS. Reg. No. 47671 (does not depict the salt form)
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • You have adjusted the weight of API as per salt factor; revise Tamoxifen as Citrate to Tamoxifen Citrate in the master formula. • Revise the pharmacological group to Anti-estrogens. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. •
	Decision: Approved. Registration letter will be issued after submission of revised manufacturing outline with addition of blistering and packing process, revised pharmacological group to Anti-estrogens along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
182.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Migxen Tablet 85/500mg
	Composition	Each Film Coated Tablet Contains: Sumatriptan as succinate……..…85mg Naproxen Sodium ……..…..…500mg

	Diary No. Date of R& I & fee	Dy. No. 12746 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	2's, 6's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TREXIMET (sumatriptan and naproxen sodium) tablets, film-coated. USFDA approved.
	Me-too status	Reprox 500+85mg Tablet film-coated. Reg. No. 83089
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add blistering and packing process to the manufacturing outlines. • Revise the pharmacological group. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of revised manufacturing outline with addition of blistering and packing process, revised pharmacological group along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
183.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Cyclovir Cream 5%
	Composition	Each Gram Contains: Acyclovir ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12739 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antivirals
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specs.
	Pack size & Demanded Price	5g, 10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZOVIRAX® (acyclovir) cream, for topical use 5%. USFDA approved.
	Me-too status	Ciavir 5% Cream. Reg. No. 85089
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add packing process to the manufacturing outlines. • Revise the pharmacological group to antivirals. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved. Registration letter will be issued after submission of revised manufacturing outline with addition of packing process, revised pharmacological group along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
184.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Cyclovir ointment 5%

	Composition	Each Gram Contains: Acyclovir ……50mg
	Diary No. Date of R& I & fee	Dy. No. 12740 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	5g, 10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZOVIRAX® (acyclovir) ointment, for topical use 5%. USFDA approved.
	Me-too status	Ciavir 5% Ointment. Reg. No. 85088
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Add packing process to the manufacturing outlines. • Revise the pharmacological group to antivirals. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved. Registration letter will be issued after submission of revised manufacturing outline with addition of packing process, revised pharmacological group along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
185.	Name and address of manufacturer / Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Soquin Cream 4% w/w
	Composition	Each Gram of Cream Contains: Hydroquinone ……4gm
	Diary No. Date of R& I & fee	Dy. No. 12742 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10g, 15g, 20g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Corrector 4% Cream by M/s VIVIER CANADA INCORPORATED (Health Canada approved) Status of the product on the website of Health Canada is "***Cancelled Post Market***"
	Me-too status	Hydrofair Cream 4% by M/s Scotmann (Reg#028278)
	GMP status	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the label claim from Hydroquinone…4gm to Hydroquinone…40mg. • You have not mentioned any emulsifying agent. Clarify. • Add packing process to the manufacturing outlines. • Revise the pharmacological group. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision. Deferred for followings;	

	• **Revision of the label claim from Hydroquinone 4gm to Hydroquinone 40mg with applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Justification for not mentioning any emulsifying agent.** • **Revision of the manufacturing outlines with adding packing process.** • **Revise the pharmacological group.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
186.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road, Karachi by M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Sucren Injection
	Composition	Each 5ml Ampoule Contains: Iron as Iron Sucrose ……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 12645 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	Global: Firm has submitted copy of GMP certificate dated 04-01-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in application is M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi, while it M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TIBC Building-1, PCSIR Laboratories Complex, Karachi in the DML.
		• Did not provide the name of contract receiver (manufacturer). Revised the name of manufacturer Form 5. The firm also submitted Form 5 from the manufacturer, which is not required. • Revised the label claim from Iron as Iron Sucrose…100mg to Iron Sucrose complex eq to. Elemental iron…100mg. • Undertaking at the end of Form has not been signed. Submitted signed undertaking. • Had only submitted Form 5. Submitted all the document as per enclosure of the Form along with copy of contract manufacturing agreement. • Claimed 5's pack size in the revised documents. • Justify 72.727 kg of iron sucrose for 40,000 ampules with label claim of Iron Sucrose complex eq to. Elemental iron…100mg. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications and as per following label claim: **"Each 5ml contains:**	

	Iron sucrose (iron(III)-hydroxide sucrose complex) eq. to elemental Iron …….. 100mg" • **Firm shall submit fee of Rs. 75,000 for standardization of label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board decided that registration letter will be issued after submission of valid GMP certificates of both the contract giver and contract acceptor. Moreover, firm shall submit evidence of performance of assay test on atomic absorption spectrophotometry, as recommended by USP monograph, by M/s Global Pharmaceuticals.** • **Registration Board further Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.**	
187.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road, Karachi by M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Cepime 2g Injection
	Composition	Each Vial Contains: Cefepime as HCl With L Arginine…….…2000mg
	Diary No. Date of R& I & fee	Dy. No. 12655 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Then submitted USP specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Renapime 2g Powder for solution for injection/infusion. MHRA approved
	Me-too status	Could not be confirmed.
	GMP status	regngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in application is M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi, while it M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TIBC Building-1, PCSIR Laboratories Complex, Karachi in the DML.
		• Did not provide the name of contract receiver (manufacturer). Revised the name of manufacturer Form 5. The firm also submitted Form 5 from the manufacturer, which is not required. • Undertaking at the end of Form has not been signed. Submitted signed undertaking. • Had only submitted Form 5. Submitted all the document as per enclosure of the Form along with copy of contract manufacturing agreement. • Claimed 1's pack size in the revised documents. • Justify 1% overage in the master formula. • Did not specify the excipients in the master formula. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for the following:	

	• **Provide evidence of approval of applied formulation already approved by the Registration Board with brand name, manufacturer name & registration number or elsewise applied on the prescribed form i.e. Form 5D along with applicable fee.** • **Submission of stability data as per guidelines of 293rd meeting of Registration Board.** • **Latest GMP certificate/last inspection report conducted within last three years of both the applicant and manufacturer.** • **Justify 1% overage in the master formula.** • **The firm shall submit fee of Rs. 75000/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
188.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi by M/s Global Pharamceuticals (Pvt.) Ltd., Plt # 204-205, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Iro Plus 500mg Injection
	Composition	Each Vial Contains: Deferoxamine Mesylate Lyophilized Powder ……..…500mg
	Diary No. Date of R& I & fee	Dy. No. 12646 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Iron chelating agent
	Type of Form	Form 5
	Finished Product Specification	Not submitted initially; then claimed in-house specs. Available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Desferal® deferoxamine mesylate for injection vial 500mg. USFDA approved
	Me-too status	Could not be confirmed.
	GMP status	regngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in application is M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi, while it M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TIBC Building-1, PCSIR Laboratories Complex, Karachi in the DML.
		• Did not provide the name of contract receiver (manufacturer). Revised the name of manufacturer Form 5. The firm also submitted Form 5 from the manufacturer, which is not required. • Undertaking at the end of Form has not been signed. • Had only submitted Form 5. Submitted all the document as per enclosure of the Form along with copy of contract manufacturing agreement. • Did not mention the excipients in the formulation. • The proposed route of administration is injection. • Revision of "Deferoxamine Mesylate eq. to Deferoxamine…500mg" in the label claim to "Deferoxamine Mesylate…500mg" is required. • Claimed 1's pack size in the revised documents. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for the following:	

	• **Provide evidence of approval of applied formulation already approved by the Registration Board with brand name, manufacturer name & registration number or elsewise applied on the prescribed form i.e. Form 5D along with applicable fee.** • **Submission of stability data as per guidelines of 293rd meeting of Registration Board.** • **Latest GMP certificate/last inspection report conducted within last three years of both the applicant and manufacturer.** • **Revision of "Deferoxamine Mesylate eq. to Deferoxamine…500mg" in the label claim to "Deferoxamine Mesylate…500mg" is required with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
189.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi by M/s Global Pharamceuticals (Pvt.) Ltd., Plt # 204-205, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Ertaren IV 1gm Injection
	Composition	Each Vial Contains: Ertapenem as sodium ……..…1g
	Diary No. Date of R& I & fee	Dy. No. 12644 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Then claimed innovator's specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	INVANZ® (ertapenem for injection), for intravenous or intramuscular (lyophilized powder in vial). USFDA approved
	Me-too status	Ernem Injection 1g (vial). Reg. No. 81179
	GMP status	Firm has submitted copy of GMP certificate dated 04-01-2022.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in application is M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road, Karachi, while it M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TIBC Building-1, PCSIR Laboratories Complex, Karachi in the DML.
		• Did not provide the name of contract receiver (manufacturer). Revised the name of manufacturer Form 5. • Undertaking at the end of Form has not been signed. The firm submitted signed undertaking. • Had only submitted Form 5. Submitted all the document as per enclosure of the Form along with copy of contract manufacturing agreement. • Did not mention the excipients in the formulation. • In the master formula, justify the quantity of Ertapenem sodium eq. to Ertapenem…1.046 and 1% overage. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 75000/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	

	Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.	
190.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi by M/s Global Pharamceuticals (Pvt.) Ltd., Plt # 204-205, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Teinin Injection 200mg
	Composition	Each Vial Contains: Teicoplanin Powder Sterile ……..…200mg
	Diary No. Date of R& I & fee	Dy. No. 12650 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Then claimed innovator's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Targocid 200mg powder for solution for injection/infusion or oral solution (lyophilized). MHRA approved
	Me-too status	Planin 200mg Injection (vial). Reg. No. 55188
	GMP status	regngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in application is M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi, while it M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TIBC Building-1, PCSIR Laboratories Complex, Karachi in the DML.
		• Did not provide the name of contract receiver (manufacturer). Revised the name of manufacturer Form 5. The firm also submitted Form 5 from the manufacturer, which is not required. • Undertaking at the end of Form was not signed. Submitted signed undertaking. • Had only submitted Form 5. Submitted all the document as per enclosure of the Form along with copy of contract manufacturing agreement. • Revised the label claim from Teicoplanin Powder Sterile…200mg to Teicoplanin sodium eq. to Teicoplanin…200mg. while it is "Each vial contains 200 mg teicoplanin equivalent to not less than 200,000 IU" in the reference product. • Revise the pharmacological group from glycopeptide antibiotic to Glycopeptide antibacterials • Justify 1% overage in the master formula. • Did not specify the excipients in the master formula. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for the following; • **Revision of label claim as per reference product with submission of full fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Confirmation of manufacturing facility of "Dry powder injection (Lyophilisation)" section required for the applied formulation.**	

	• **Justification of 1% overage in the master formula.** • **specify the excipients in the master formula.** • **Latest GMP certificate/last inspection report conducted within last three years of both the applicant and manufacturer.**	
191.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi by M/s Global Pharamceuticals (Pvt.) Ltd., Plt # 204-205, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Cefavi Injection 2gm
	Composition	Each Vial Contains: Ceftazidime pentahydrate Eq To Ceftazidime…..…2g Avibactam sodium Eq To Avibactam Ceftazidime ……..…0.5g
	Diary No. Date of R& I & fee	Dy. No. 12635 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVYCAZ (ceftazidime and avibactam) for injection, for intravenous us. MHRA approved
	Me-too status	Not confirmed.
	GMP status	regngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in application is M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi, while it M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TIBC Building-1, PCSIR Laboratories Complex, Karachi in the DML.
		• Had not provided the name of contract receiver (manufacturer). Revised the name of manufacturer in Form 5. • Undertaking at the end of Form was not signed. Submitted signed undertaking. • Had only submitted Form 5. Submitted all the document as per enclosure of Form 5 along with copy of contract manufacturing agreement. • Revised the pharmacological group from Cephalosporins to third generation cephalosporins. • Revised the route of administration from parentertal to intra venous. • Revised Avibactam sodium Eq To Avibactam Ceftazidime…0.5g to Avibactam sodium Eq To Avibactam…0.5g • Submit your application on Form 5D along with stability studies as per zone IV-A. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for the following: • **Provide evidence of approval of applied formulation already approved by the Registration Board with brand name, manufacturer name & registration number or elsewise applied on the prescribed form i.e. Form 5D along with applicable fee.**	

	• **Submission of stability data as per guidelines of 293rd meeting of Registration Board.** • **Submission of Finished Product Specification.** • **Latest GMP certificate/last inspection report conducted within last three years of both the applicant and manufacturer.** • **Submission of full fee for correction in the label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
192.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi by M/s Vision Pharmaceuticals, Plot # 22-23, Industrial Triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vancoren 1gm Injection
	Composition	Each Vial Contains: Vancomycin as HCl……..…1g
	Diary No. Date of R& I & fee	Dy. No. 12643 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Then claimed USP specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	VANCOCIN CP vancomycin 1g (1,000,000IU as hydrochloride) powder for injection vial. TGA approved
	Me-too status	Vanzy 1g Injection. Reg. No. 81902
	GMP status	regngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in application is M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi, while it M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TIBC Building-1, PCSIR Laboratories Complex, Karachi in the DML.
		• Did not provide the name of contract receiver (manufacturer). Revised the name of manufacturer Form 5. The firm also submitted Form 5 from the manufacturer, which is not required. • Undertaking at the end of Form has not been signed. The firm submitted signed undertaking. • Had only submitted Form 5. Submitted all the document as per enclosure of Form 5 (**meant for 500mg**) of the Form along with copy of contract manufacturing agreement. Did not adjust the weight of API as per salt factor in the master formula. • Did not mention the excipients in the formulation. • Claimed a pack size of 1x1's in the revised documents. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for the following; • **Confirmation of manufacturing facility required for the applied formulation.** • **Adjust the weight of API as per salt factor in the master formula.** • **Excipients in the formulation.** • **Latest GMP certificate/last inspection report conducted within last three years of both the applicant and manufacturer.**	

	• **Submission of the applicable fee for correction/changes as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
193.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Dexanil 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets Enteric Coated Eq To Dexlansoprazole …….…….30mg
	Diary No. Date of R& I & fee	Dy. No. 13050 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	VANCOCIN CP vancomycin 1g (1,000,000IU as hydrochloride) powder for injection vial. TGA approved
	Me-too status	Vanzy 1g Injection. Reg. No. 81902
	GMP status	regngmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The address in application is M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road, Karachi, while it M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TIBC Building-1, PCSIR Laboratories Complex, Karachi in the DML. • The firm submitted Rs. 10,000/- fee (challan No. 7896172330).
		• The applied brand name is Dexanil 60mg Capsule. Clarify. • Specify the capsule shell material in the composition. • Specify the source of pellets. • For above revisions, submit the applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit stability studies as per zone IV-A. • The firm replied that they have submitted the stability data. The matter was referred to PEC for evaluation of stability data on its turn.
	Decision: Deferred for the following; • **Specify the capsule shell material in the composition.** • **Source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.** • **Latest GMP certificate/last inspection report conducted within last three years.** • **Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.**	
194.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Jovin 500mg/400mg Tablet
	Composition	Each Film Coated Tablet Contains: Glucosamine HCl ……..…500mg Chondroitin Sulphate ……400mg
	Diary No. Date of R& I & fee	Dy. No. 12681 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Glucoaminoglycan
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Glucotin Tablets. Reg. No. 64400 (corrected in 271-M of RB from glucosamine sulfate to glucosamine HCl). The matter of sodium chloride still remains unclear.
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Undertaking at the end of Form 5 is missing. • Revise the pharmacological group to Factor Xa inhibitor. • Provide proof of reference product (brand name and market authorization holder, with same strength and formulation) in reference regulatory agencies as defined in 275th meeting of the registration Board. • Provide proof of me-too product (name and registration number with same salt form) already approved by DRAP. • You have claimed USP specifications for the drug product. Provide proof that the product monograph is available in the latest edition of USP. • For above revisions, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Latest GMP certificate/last inspection report conducted within last three years.**	
195.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zolpro forte 20mg
	Composition	Each Sachet Contains: Omeprazole ……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 12280 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP old edition, not in latest
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	sfephmgmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• You have applied for omeprazole 20mg sachet. Submit properly filled enclosure of Form 5. • Submit the composition with list of excipients and manufacturing outlines. • Submit drug product specifications.

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Provide proof of international availability in the reference regulatory agencies as defined by the registration board in its 275th meeting. • Proof of me-too product (name and registration number) already approved by DRAP is required.
	Decision: Deferred for following; • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **Latest GMP certificate/last inspection report conducted within last three years.** • **Submission of Pharmacological Group for the applied formulation.** • **Submission of composition with list of excipients and manufacturing outlines.** • **Submission of finished drug product specifications.**	
196.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zolpro forte 40mg
	Composition	Each Sachet Contains: Omeprazole…40mg
	Diary No. Date of R& I & fee	Dy. No. 12281 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP old edition, not in latest
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	GMP certificate issued on 13.08.2022
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• You have applied for omeprazole 40mg sachet. Submit properly filled enclosure of Form 5. • Submit the composition with list of excipients and manufacturing outlines. • Submit drug product specifications. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Provide proof of international availability in the reference regulatory agencies as defined by the registration board in its 275th meeting. • Proof of me-too product (name and registration number) already approved by DRAP is required.
	Decision: Deferred for following; • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **Latest GMP certificate/last inspection report conducted within last three years.** • **Submission of composition with list of excipients and manufacturing outlines.** • **Submission of Pharmacological Group for the applied formulation.** • **Submission of finished drug product specifications.**	
197.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK

		By M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gennifer P Injection 100mg/5ml (IV)
	Composition	Each 5ml Ampoule Contains: Iron As III hydroxide polymaltose complex…100mg
	Diary No. Date of R& I & fee	Dy. No. 12662 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Iron parenteral preparations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs. Not available in USP
	Pack size & Demanded Price	5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FERROSIG INJECTION iron 100mg/2mL (as polymaltose) injection ampoule, TGA Approved
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the pharmacological group from Iron supplement to Iron, parenteral preparations. • You have applied for Iron as III Hydroxide Polymaltose Complex…100mg. Revise the label claim in line with the reference product and adjust the weight of API as per salt factor in master formula. • Specify the excipients for the pH adjustment. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • You have claimed USp specifications. Provide proof that the drug product is available in USP. • Provide proof of international availability in the reference regulatory agencies as defined by the registration board in its 275th meeting. • Proof of me-too product (name and registration number) already approved by DRAP is required. • Submit latest GMP inspection reports of both the firms. • Submit copy of DMLs of both the firms.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **Reference of drug product specifications.**	
198.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK By M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gennifer Injection 100mg/5ml (IV)
	Composition	Each 5ml Ampoule Contains: iron as sucrose ……100mg Eq. to iron……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 12663 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Iron parenteral preparations
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	5's (5ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule, TGA Approved
	Me-too status	Ferrodin Injection 100mg/5ml. reg. No. 84670
	GMP status	genomgmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The TGA has used the term Iron sucrose for the iron(III) hydroxide sucrose complex.
		• Revised the pharmacological group from Iron supplement to Iron, parenteral preparations. • Applied for Each 5ml Ampoule Contains: iron as sucrose…100mg Eq. to iron…100mg. Revised the label claim to iron as iron sucrose…100mg in line with the reference product and adjust the weight of API as per salt factor in master formula. • No excipients were mentioned. Specified the excipients for the pH adjustment. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Registration Board in its 288th meeting upon detailed deliberation of capacity assessment report and considering the measures taken by the firm for upgradation of QC lab decided to allow contract manufacturing by M/s EG Pharmaceuticals, Industrial Triangle Kahuta Road, Islamabad
	Decision: Approved. Registration letter will be issued upon submission of following: • **Revised label claim as per innovator product alongwith submission of 75,000/- fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP certificate/last inspection report conducted within last three years for both applicant and manufacturer.**	
199.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK By M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Citonome 1g/4ml Injection
	Composition	Each 4ml Ampoule Contains: Citicoline As Sodium eq to Citicoline …….. …1g
	Diary No. Date of R& I & fee	Dy. No. 12665 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	5's (5ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	CITICOLINA GIT 1000mg / 4ml solution for injection (vial 4ml), AIFA approved
	Me-too status	Coleen Injection.1000mg/4ml. Reg. No. 46760
	GMP status	genomgmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from neurotonic/nootropic to "Other psychostimulants and nootropics". • Applied for Each 4ml Ampoule Contains: Citicoline As Sodium eq to Citicoline …1g.

		Revised the label claim to Each 4ml Ampoule Contains: Citicoline As Sodium ……1g. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Registration Board in its 288th meeting upon detailed deliberation of capacity assessment report and considering the measures taken by the firm for upgradation of QC lab decided to allow contract manufacturing by M/s EG Pharmaceuticals, Industrial Triangle Kahuta Road, Islamabad
	Decision: Approved with innovator's specifications. **Registration letter will be issued upon submission of latest GMP certificate/last inspection report conducted within last three years for both applicant and manufacturer.**	
200.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK By M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Piranome 1g/5ml Injection
	Composition	Each 5ml Ampoule Contains: Piracetam ……..…1g
	Diary No. Date of R& I & fee	Dy. No. 12659 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	12's (5ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	DIZZITAM 200 mg / ml oral and injectable solution for intravenous use (5ml, 10ml ampoule), AIFA approved
	Me-too status	Neurotam Injection. Reg. No. 7348
	GMP status	genomgmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The firm revised the pharmacological group from anticonvulsant to "Other psychostimulants and nootropics". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. Registration Board in its 288th meeting upon detailed deliberation of capacity assessment report and considering the measures taken by the firm for upgradation of QC lab decided to allow contract manufacturing by M/s EG Pharmaceuticals, Industrial Triangle Kahuta Road, Islamabad
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for pre-registration correction/change as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP inspection report conducted within last three years for both applicant and manufacturer.**	
201.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK By M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lacgen 30mg/ml Injection

	Composition	Each ml Ampoule Contains: Ketoralac Tromethamine eq to Ketoralac Tromethamine ……..…30mg
	Diary No. Date of R& I & fee	Dy. No. 12666 dated 06.03.2019 Rs. 50,000/- dated 06.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	5's (1ml ampoule); As per SRO
	Approval status of product in Reference Regulatory Authorities.	TORADOL ketorolac trometamol 30mg/1mL (ketorolac trometamol 30mg without equivalency) injection ampoule. TGA approved.
	Me-too status	Syntor 30 mg Injection IV/IM. Reg. No. 83365
	GMP status	genomgmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Applied for Ketorolac Tromethamine eq to Ketorolac Tromethamine…30mg. Revised the label claim to Ketorolac Tromethamine…30mg. • Revise the pharmacological group from NSAIDs to "Acetic acid derivatives and related substances". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. **Revised label claim is as under;** **Each ml Ampoule Contains:** **Ketorolac Tromethamine ……..…30mg**
	Decision: Registration Board deferred the case for further deliberation regarding the sterilization method of the applied formulation whether by way of terminal sterilization or otherwise.	
202.	Name and address of manufacturer / Applicant	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Redicort cream 1%, 1% w/w
	Composition	Each Gram Contains: Clotrimazole ……..…10mg 11.2 mg Hydrocortisone Acetate eq. to 10mg hydrocortisone
	Diary No. Date of R& I & fee	Dy. No.11762 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	hydrocortisone, combinations
	Type of Form	Form 5
	Finished Product Specification	Not submitted. available in BP.
	Pack size & Demanded Price	10g; Leader price
	Approval status of product in Reference Regulatory Authorities.	Canesten Hydrocortisone Canesten Hydrocortisone (with salt equivalent) Athlete's Foot 1%, 1% w/w Cream. MHRA approved
	Me-too status	Aquazole Cream 10gm (without salt equivalent). (Reg#067931)
	GMP status	rmggmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the pharmacological group from antifungal to hydrocortisone, combinations. • You have mentioned eye ointment form in the manufacturing outlines. Justify. • You have mentioned NLT 5G filling, but the applied pack size is 10g. Clarify. • Submit drug product specifications.

		• For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with BP specifications. Registration letter will be issued after submission of revised pharmacological group, revised manufacturing outlines with fee of 7500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • **Firm shall also submit latest GMP certificate/last inspection report conducted within last three years.**	
203.	Name and address of manufacturer / Applicant	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Fusirem Cream 2%
	Composition	Each Gram Contains: Fusidic Acid ……20mg
	Diary No. Date of R& I & fee	Dy. No.11742 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Other antibiotics for topical use
	Type of Form	Form 5
	Finished Product Specification	The firm has submitted copy of BP specs. available in BP.
	Pack size & Demanded Price	5g, 10g; Leader price
	Approval status of product in Reference Regulatory Authorities.	Fucidin 20 mg/g Cream. MHRA Approved
	Me-too status	FUCIDIN CREAM 20mg. Reg. No. 15539
	GMP status	rmggmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• You have mentioned NLT 5G filling, but the applied pack size is 10g. Clarify. • You have mentioned eye ointment form in the manufacturing outlines. Justify. • Submit drug product specifications. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with BP specifications. Registration letter will be issued after submission of revised manufacturing outlines with fee of 7500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • **Firm shall also submit latest GMP certificate/last inspection report conducted within last three years.**	
204.	Name and address of manufacturer / Applicant	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Retaval cream 0.1%
	Composition	Each Gram Contains: Betamethasone as Valerate ……1mg
	Diary No. Date of R& I & fee	Dy. No.11754 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	The firm has submitted copy of BP specs. available in BP.
	Pack size & Demanded Price	5g, 10g; Leader price
	Approval status of product in Reference Regulatory Authorities.	Betamethasone (as) Valerate 0.1%w/w Cream. MHRA Approved
	Me-too status	Beason Cream 0.1%. Reg. No. 80082
	GMP status	rmggmp

	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Mentioned NLT 15g filling, but the applied pack size is 5g and 15g. then, revised it. • Submitted Rs. 7500/- fee challan- 208859634230.
	Decision: Approved with BP specifications. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
205.	Name and address of manufacturer / Applicant	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Retaval Lotion 0.1%
	Composition	Each Gram Contains: 1% lotion contains 1.2mg of Betamethasone Valerate (eq. to 1mg Betamethasone)
	Diary No. Date of R& I & fee	Dy. No.11756 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	The firm has submitted copy of BP specs. available in BP.
	Pack size & Demanded Price	60ml; Leader price
	Approval status of product in Reference Regulatory Authorities.	Betnovate Lotion (Betamethasone Valerate 0.122% w/w). MHRA Approved
	Me-too status	B.M.T Lotion 0.1%/gm. Reg. No. 72710
	GMP status	rmggmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Applied for w/w, however, the master formula and pack size were mentioned in ml. then, revised it to grams. • Submitted Rs. 7500/- fee challan- 27671491529
	Decision: Approved with BP specifications. Registration letter will be issued after submission of latest GMP certificate/last inspection report conducted within last three years.	
206.	Name and address of manufacturer / Applicant	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Tacilus Ointment 0.1%
	Composition	Each Gram Contains: Tacrolimus as Monohydrate ……..…0.1%
	Diary No. Date of R& I & fee	Dy. No.11759 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Calcipotriol, Combinations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs. available in BP.
	Pack size & Demanded Price	10g, 30g; Leader price
	Approval status of product in Reference Regulatory Authorities.	Tacrolimus Accord 0.1 % ointment. MHRA approved
	Me-too status	Limus 0.1% Ointment. Reg. No. 45215
	GMP status	rmggmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the pharmacological group from dermatologicals to "Agents for dermatitis, excluding corticosteroids". • You have mentioned NLT 5g filling, but the applied pack size is 10g and 30g. Clarify. • You have mentioned eye ointment form in the manufacturing outlines. Justify

		• For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board approved registration of product with innovator's specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. • **Registration letter will be issued after submission of revised the pharmacological group from dermatological to "Agents for dermatitis, excluding corticosteroids, revised manufacturing outlines with submission of fee of 7500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
207.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Lsprd 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12208 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Benzamides
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	1x10's, 3x10's, 6x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	LEVOPRAID® 50 mg Tablets by TEOFARMA Srl. Approved by AIFA
	Me-too status	Sulvo Tablets 50mg. Reg. No. 31748
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Submitted form 5 and its enclosures are for Itopride HCL instead of Levosulpiride.
	Decision: Deferred for submission of all the enclosures of Form 5 for the applied formulation along with submission of apllicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
208.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Mosmd 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide ……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 12212 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Aspire 100 mg film-coated tablets by Aspire Pharma Limited. **MHRA** Approved
	Me-too status	Lalap 100mg Tablet by Genix Pharma (Pvt.) Ltd. Reg. No. 70471
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.

		• Firm has submitted all the enclosures of form 5. However, specifications for the finished drug product are not provided.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
209.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Mosmd 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12211 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Aspire 50 mg film-coated tablets by Aspire Pharma Limited. **MHRA** Approved
	Me-too status	Lalap 50mg Tablet by Genix Pharma (Pvt.) Ltd. Reg. No. 70470
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Firm has submitted all the enclosures of form 5. However, specifications for the finished drug product are not provided.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
210.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Mosmd 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide……..…150mg
	Diary No. Date of R& I & fee	Dy. No. 12213 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Accord 150 mg film-coated tablets. MHRA approved.
	Me-too status	Lacolep 150mg Tablet Reg. No. 73859
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form has not been signed. • Firm has submitted all the enclosures of form 5. However, specifications for the finished drug product are not provided.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	

211.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Ondan 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron as Ondansetron HCl dihydrate……8mg
	Diary No. Date of R& I & fee	Dy. No. 12209 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 8mg. Reg No. 82657
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The firm mentioned the pharmacological group as selective Serotonin (5HT3) antagonists.
		• Firm has submitted all the enclosures of form 5. However, form 5 is unsigned.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of 7500/- fee for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
212.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Pelip 3mg Tablet
	Composition	Each Sustained Release Tablet Contains: Paliperidone……..…3mg
	Diary No. Date of R& I & fee	Dy. No. 12215 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	INVEGA (1.5mg, 3mg, 6mg, 9mg) Extended-Release Tablets USFDA approved
	Me-too status	Vegadon SR 3mg Tablets. Reg. No. 080371
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The reference product Invega, approved by USFDA is Extended release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. Provide evidence of required manufacturing technology as per reference product, and revise the manufacturing outlines accordingly.
		• Firm has submitted signed form 5 along with all the enclosures of form 5.
	Decision: Deferred for following: • **Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product.**	

213.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Pelip 6mg Tablet
	Composition	Each Sustained Release Tablet Contains: Paliperidone……6mg
	Diary No. Date of R& I & fee	Dy. No. 12216 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	INVEGA (1.5mg, 3mg, 6mg, 9mg) Extended-Release Tablets USFDA approved
	Me-too status	Vegadon SR 6mg Tablets. Reg. No. 080372
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The reference product Invega, approved by USFDA is Extended release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. Provide evidence of required manufacturing technology as per reference product.
		• Firm has submitted signed form 5 along with all the enclosures of form 5.
	Decision: Deferred for following: • **Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product.**	
214.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Moprostl 200mcg
	Composition	Each Tablet Contains: Misoprostol……..…200mcg
	Diary No. Date of R& I & fee	Dy. No. 12214 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Prostaglandins.
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in IP and BP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CYTOTEC Misoprostol 200 microgram tablet, uncoated. TGA approved
	Me-too status	Misoclear Tablets 200mcg. Reg. No. 84191
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the pharmacological group from Prostaglandin analogues to Prostaglandins. • Firm has submitted signed form 5 along with all the enclosures of form 5.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of submission of 75,00/- fee for pre-registration correction/change as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	

	• **Firm will also submit revised pharmacological group with pre-registration variation fee.**	
215.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Sapride 50mg
	Composition	Each Tablet Contains: Itopride HCl……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12204 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Antiemetics, Prokinetics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Itopride hydrochloride tablet 50 mg. **PMDA** approved
	Me-too status	Itoride Tablet by Lexicon Pharmaceutical. Reg No. 42040
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the pharmacological group from Prostaglandin analogues to Prostaglandins. • Revise the label claim from Each Tablet Contains: Itorpide Hcl…50mg to Each film-coated Tablet Contains: Itorpide Hcl…50mg. • Firm has submitted signed form 5 along with all the enclosures of form 5. Firm has revised their label claim from each tablet contains Itorpide HCl…50mg to each tablet contains Itorpide as Itopride HCl…50mg without submission of any fee. Furthermore, no finished product specifications are submitted.
	Decision: Approved with innovator's specifications and following label claim; **Each film coated Tablet Contains:** **Itopride as HCl……50mg** • **Registration letter will be issued after submission of submission of 30,000/- fee for pre registration correction/change as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
216.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	SDOLP 37.5mg/325mg Tablet
	Composition	Each Tablet Contains: Tramadol HCl……..37.5mg Paracetamol……325mg
	Diary No. Date of R& I & fee	Dy. No. 12204 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms US-FDA approved
	Me-too status	Tril-P Tablet by Linta Pharmaceuticals. Reg. No. 78181

	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the pharmacological group to Opioids in combination with non-opioid analgesics. • Revise the label claim to film-coated tablet. • Firm has submitted form 5 along with all the enclosures of form 5. However, firm has neither revised the pharmacological group the label claim of the applied formulation.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of submission of 7500/- fee for pre registration correction/change as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also submit revised label claim from uncoated tablets to film coated tablet and revised the pharmacological group for the applied formulation with pre-registration variation fee.**	
217.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Telam tablet 5/40mg
	Composition	Each Tablet Contains: Amlodipine As Besylate……5mg Telmisartan…….40mg
	Diary No. Date of R& I & fee	Dy. No. 12201 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Angiotensin II antagonists and calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (5/40mg). TGA approved
	Me-too status	Ezitab-AM Tablet. Reg. No. 082041
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Submit all the requirements /documents as per enclosure of Form 5 along with submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for submission of all the requirements /documents as per enclosure of Form 5 along with submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
218.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Telam tablet 5/80mg
	Composition	Each Tablet Contains: Amlodipine As Besylate……5mg Telmisartan……..80mg
	Diary No. Date of R& I & fee	Dy. No. 12202 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Angiotensin II antagonists and calcium channel blocker
	Type of Form	Form 5

	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (5/80mg). TGA approved
	Me-too status	Ezitab-AM Tablet. Reg. No. 082044
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Submit all the requirements /documents as per enclosure of Form 5 along with submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for submission of all the requirements /documents as per enclosure of Form 5 along with submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
219.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Telam tablet 10/40mg
	Composition	Each Tablet Contains: Amlodipine As Besylate…10mg Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy. No. 12203 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Angiotensin II antagonists and calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (10/40mg). TGA approved
	Me-too status	Ezitab-AM Tablet. Reg. No. 082045
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Submit all the requirements /documents as per enclosure of Form 5 along with submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for submission of all the requirements /documents as per enclosure of Form 5 along with submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
220.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Smval 10/160mg Tablets
	Composition	Each Tablet Contains: Amlodipine Besylate……10mg Valsartan……160mg
	Diary No. Date of R& I & fee	Dy. No. 12203 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Angiotensin II antagonists and calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	14's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Amlodipine/Valsartan 10 mg/160 mg film-coated tablets, MHRA approved.
	Me-too status	Exforge 10/160mg tablet, Novartis Pharma (Import), Reg. No. 047571.
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the formulation from tablet to film-coated tablet. • Revise Amlodipine Besylate…10mg to Amlodipine as Besylate…10mg. • Firm has submitted signed form 5 along with all the enclosures of form 5. However, no change is made in the label claim and coated tablets.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of submission of 30,000/- fee for pre-registration correction/change as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Firm will also submit revised label claim as per reference product from Amlodipine Besylate…10mg to Amlodipine as Besylate…10mg and revision of formulation from uncoated to film coated tablets.**	
221.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Sinita 1mg Tablet
	Composition	Each Tablet Contains: Cinitapride Hydrogen Tartrate……1mg
	Diary No. Date of R& I & fee	Dy. No. 12205 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cinitapride Cinfa 1 mg uncoated tablets (Spain Approved)
	Me-too status	Cidine 1mg tablet by highnoon laboratories
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise Cinitapride Hydrogen Tartrate…1mg to Cinitapride as Hydrogen Tartrate…1mg. • Firm has submitted signed form 5 along with all the enclosures of form 5. Firm has also revised their label claim as per reference product without submission of applicable fee. However, specifications for the finished product are not submitted. **Revised label claim is as under;** **Each Tablet Contains:** **Cinitapride as Hydrogen Tartrate……1mg**
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of submission of 30,000/- fee for pre-registration correction/change as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
222.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Slrnx 8mg

	Composition	Each Film Coated Tablet Contains: Lornoxicam……..…8mg
	Diary No. Date of R& I & fee	Dy. No. 12210 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the formulation from tablet to film-coated tablet. • Firm has submitted signed form 5 along with all the enclosures of form 5. However, specifications for the finished product are not submitted.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of submission of 7500/- fee for pre-registration correction/change as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
223.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Mapdon 4mg/5ml Syrup
	Composition	Each 5ml Contains: Ondansetron HCl Dihydrate…….4mg
	Diary No. Date of R& I & fee	Dy. No. 12225 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	50ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron (as the hydrochloride dihydrate) 4mg/5ml Syrup. MHRA Approved
	Me-too status	Ondan syrup 4mg/5ml, Bio-mark pharmaceutical, Reg. No. 082628.
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Firm has submitted signed form 5 along with all the enclosures of form 5. Firm has also revised their label claim as per reference product without submission of applicable fee. However, specifications for the finished product are not submitted. **Revised label claim is as under;** **Each 5ml Contains:** **Ondansetron as hydrochloride Dihydrate….4mg**
	Decision: Approved with USP specifications. Registration letter will be issued after submission of submission of 30,000/- fee for pre-registration correction/change as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
224.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Saprofen 200mg/5ml

	Composition	Each 5ml Contains: Ibuprofen……..…200mg
	Diary No. Date of R& I & fee	Dy. No. 12224 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Non-selective COX inhibitors
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	90ml, 450ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ibuprofen 100mg/5ml Suspension, MHRA approved.
	Me-too status	Tercica 100mg/5ml Suspension, Sami, Karachi, Reg. No. 061206
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Firm has submitted signed form 5 along with all the enclosures of form 5. • In initially submitted dossier firm has claimed each 5ml contains 200mg of Ibuprofen. However, in newly submitted enclosures of Form 5 they revised their label claim to each 5ml contains 100mg of Ibuprofen. • They have claimed BP specs.
	Decision: Deferred for clarification of the label claim for the applied formuation.	
225.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Sinita 2mg/ml syrup
	Composition	Each ml Contains: Cinitapride Hydrogen Tartrate……..…2mg
	Diary No. Date of R& I & fee	Dy. No. 12226 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	90ml, 450ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg/5 ml Oral solution, CIMA approved.
	Me-too status	Gutt oral solution. Reg. No. 75278
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The pharmacological group has not been provided. Mention it as Propulsives. • Revise Each ml Contains: Cinitapride Hydrogen Tartrate…2mg to Each 5ml Contains: Cinitapride as Hydrogen Tartrate…1mg, and fill serial No. 04 of the enclosure accordingly. • You have provided the pack size as 1x14's tablet. Jsutify/revise. • Submit all the requirements /documents as per enclosure of Form 5 along with submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for the following;	

	• **Pharmacological group for the applied formulation.** • **Revision of label claim as per reference product along with submission of full fee.** • **Revision of pack size from tablet to syruo formulation.** • **Submission of all the requirements /documents as per enclosure of Form 5.**	
226.	Name and address of manufacturer / Applicant	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore By M/s Shahzeb Pharmaceuticals Hazara Trunk Road, Sarai Gadaee Haripur. KPK
	Brand Name +Dosage Form + Strength	Dee Injection 5mg IM / oral
	Composition	Each Ampoule Contains: Cholecalciferol (Vitamin D3)…5mg (200,000 IU)
	Diary No. Date of R& I & fee	Dy. No. 13048 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Vitamin D
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	1's (HDPE ampule) 1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VITAMINE D3 BON 200 000 U.I. / 1 ml, solution injectable IM en ampoule (glass). **ANSM** approved
	Me-too status	Accu-D Injection. Reg. No. 79755
	GMP status	srqgmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The provided reference product is packed in glass ampoule. You have applied for HDPE ampoule. Justify. • You have not provided the strength of the product. • Submit compostion (with list of excipients), master formula and manufacturing outlines. • Submit contract manufacturing agreement. • Manufacturer in enclosure of Form 5 is Highnoon Laboratories. Revise it. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following; • **Justification for using HDPE ampoule while the reference product is packed in glass ampoule.** • **Submission of complete compostion (with list of excipients), master formula and manufacturing outlines.** • **Copy of the contract agreement.** • **Revision of manufacturer in the enclosure of Form 5 where M/s Highnoon Laboratories is mentioned as manufacturer** • **submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.** • **Latest GMP certificate/ last inspection report conducted within last three years of both the applicant and manufacturer.**	
227.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Colin Injection 1MIU
	Composition	Each Vial Contains: Colistimethate Sodium……..…1MIU
	Diary No. Date of R& I & fee	Dy. No.12092 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Antibacterials
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.

	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection (lyophilized powder in glass vial). Approved by **MHRA**
	Me-too status	Colistat powder for Injection. Reg. No. 76160
	GMP status	The firm was inspected on 12.12.2018, GMP was reported at satisfactory level. GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 shall be submitted by the applicant, not manufacturer. • Specify the applicant as well as manufacturer in enclosure of Form 5. • The reference product is lyophilized powder. The submitted documents does not depict the same. Clarification is required. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following; • **Latest GMP certificate/ last inspection report conducted within last three years.** • **Form 5 shall be submitted by the applicant, not manufacturer.** • **Clarification regarding the manufacturing method of the applied formulation as reference product is lyophilized powder.** • **Deferred for confirmation of required manufacturing facility / section from Licensing Division.**	
228.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Deson 4mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Dexamethasone Phosphate (as sodium)…….4.4mg
	Diary No. Date of R& I & fee	Dy. No.12095 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Glucocorticoids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	25'sx1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	DBL DEXAMETHASONE SODIUM PHOSPHATE INJECTION 4mg/1mL (as sodium) injection ampoule. TGA approved
	Me-too status	Histopak Injection. Reg. No. 57655
	GMP status	The firm was inspected on 12.12.2018, GMP was reported at satisfactory level. GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 shall be submitted by the applicant, not manufacturer. • Specify the applicant as well as manufacturer in enclosure of Form 5. • Revise Dexamethasone Phosphate (as sodium) 4.4mg to Dexamethasone Phosphate (as sodium)…4mg in the label claim.

		• Revise Dexamethasone Phosphate as sodium…4.4mg to Dexamethasone Phosphate sodium…4.37mg in the master formula. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit GMP inspection reports of both the firms.
	Decision: Deferred for following: • **Confirmation of approval of required manufacturing facility Licensing Division.** • **Revision of label claim as per innovator product along with submission of applicable fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Capacity assessment of M/s Rotex Pharma Pvt. Ltd.**	
229.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Drocort 100mg Injection
	Composition	Each Vial Contains: Hydrocortisone Sodium Succinate eq. to Hydrocortisone……..…100mg
	Diary No. Date of R& I & fee	Dy. No.12093 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Glucocorticoids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	HYDROCORTISONE PANPHARMA hydrocortisone as sodium succinate 100 mg powder for injection vial. TGA approved
	Me-too status	Cortizone 100mg Injection. Reg. No. 81898
	GMP status	The firm was inspected on 12.12.2018, GMP was reported at satisfactory level. GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 shall be submitted by the applicant, not manufacturer. • Specify the applicant as well as manufacturer in enclosure of Form 5. • Revise "Hydrocortisone Sodium Succinate eq. to Hydrocortisone" to Hydrocortisone Sodium Succinate" in the composition master formula only. • Mentioned the excipients in the composition. • The reference product is a freeze-dried cake. You have not submitted the lyophilization procedure and provision of facility thereof. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for the following; • **Form 5 shall be submitted by the applicant, not manufacturer.** • **Specify the applicant as well as manufacturer in enclosure of Form 5.** • **Revise salt form as per innovator drug product.** • **Approval of Licensing Division for lyophilization facility.**	

	• **For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021** • **Capacity assessment of M/s Rotex Pharma Pvt. Ltd.**	
230.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Drocort 250mg Injection
	Composition	Each Vial Contains: Hydrocortisone Sodium Succinate eq. to Hydrocortisone…250mg
	Diary No. Date of R& I & fee	Dy. No.12094 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	Glucocorticoids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	HYDROCORTISONE PANPHARMA hydrocortisone as sodium succinate 250 mg powder for injection vial. TGA approved
	Me-too status	Cortizone 250mg Injection. Reg. No. 81899
	GMP status	The firm was inspected on 12.12.2018, GMP was reported at satisfactory level. GMP certificate issued on the basis of inspection dated 12.08.2020.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Form 5 shall be submitted by the applicant, not manufacturer. • Specify the applicant as well as manufacturer in enclosure of Form 5. • Revise "Hydrocortisone Sodium Succinate eq. to Hydrocortisone" to Hydrocortisone Sodium Succinate" in the composition master formula only. • Mentioned the excipients in the composition. • The reference product is a freeze-dried cake. You have not submitted the lyophilization procedure and provision of facility thereof. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for the following; • **Form 5 shall be submitted by the applicant, not manufacturer.** • **Specify the applicant as well as manufacturer in enclosure of Form 5.** • **Revise salt form as per innovator drug product.** • **Approval of Licensing Division for lyophilization facility.** • **For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021** • **Capacity assessment of M/s Rotex Pharma Pvt. Ltd.**	
231.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Bical 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Bicalutamide……..…50mg
	Diary No. Date of R& I & fee	Dy. No.12289 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019

	Pharmacological Group	Anti-androgens
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP and BP
	Pack size & Demanded Price	25's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bicalutamide 50mg filmcoated tablets. MHRA approved.
	Me-too status	Calutide-50 Tablet. Reg. No. 45650
	GMP status	semsgmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The structure does not contain steroid nucleus.
		•
	Decision: Registration Board rejected the application of the firm since the firm does not have the required manufacturing facility for the applied formulation.	
232.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Besol 2mg Tablet
	Composition	Each Film Coated Tablet Contains: Chlorambucil……2mg
	Diary No. Date of R& I & fee	Dy. No.12290 dated 06.03.2019 Rs. 20,000/- dated 05.03.2019
	Pharmacological Group	Anticancer
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP and BP
	Pack size & Demanded Price	25's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Chlorambucil 2 mg filmcoated tablets. MHRA approved.
	Me-too status	Leukeran tablets 2mg. Reg. No. 11511
	GMP status	semsgmp
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		•
	Decision: Registration Board rejected the application of the firm since the firm does not have the required manufacturing facility for the applied formulation.	
233.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Triwim Cream
	Composition	Each Gram Contains: Fluocinolone Acetonide …. 0.1mg Hydroquinone …… 40mg Tretinoin ……..… 0.5mg
	Diary No. Date of R& I & fee	Dy. No.12132 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10g, 15g, 30g, 45g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRI-LUMA® (fluocinolone acetonide, hydroquinone, and tretinoin) cream, 0.01%, 4%, 0.05% for topical use by Galderma Labs LP. USFDA approved
	Me-too status	Trimelasin Cream by Valor Pharmaceuticals. Reg. No. 31104

	GMP status	cGMP certificate on the basis of evaluation conducted on 08-09-2021
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise pharmacological group to Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit latest GMP inspection report. Firm has submitted Form 5 with corrected pharmacological group as Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use along with submission of fee of Rs. 7,500/- vide deposit slip# 91777507459
	Decision: Approved with innovator's specifications.	
234.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Fuci-Mit 2% w/w Ointment
	Composition	Each Gram Contains: Sodium Fusidate …… 20mg
	Diary No. Date of R& I & fee	Dy. No.12128 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specifications.
	Pack size & Demanded Price	15g, 30g, 45g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FUCIDIN sodium fusidate 20mg/g ointment tube. TGA Approved
	Me-too status	Fusiderm Ointment 2%. Reg. No. 26749
	GMP status	cGMP certificate on the basis of evaluation conducted on 08-09-2021
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• You have applied for ointment, however, the submitted composition are meant for o/w emulsion. Clarify. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Firm has submitted master formulation with submission of fee of Rs. 7,500/- vide deposit slip# 075033962
	Decision: Approved.	
235.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Betawit C ointment
	Composition	Each Gram Contains: Betamethasone (as dipropionate) … 0.5mg Calcipotriol (as monohydrate)… 50mcg
	Diary No. Date of R& I & fee	Dy. No.12128 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Corticosteroids + Antibiotics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	15g, 30g; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Calcipotriol (as monohydrate) /Betamethasone (as dipropionate) Sandoz 50 micrograms per g / 500 micrograms per g ointment. MHRA approved.
	Me-too status	Calbet Ointment. Reg. No. 84025
	GMP status	cGMP certificate on the basis of evaluation conducted on 08-09-2021
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revise the pharmacological group from Corticosteroids + Antibiotics to Other antipsoriatics for topical use. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Firm has submitted Form 5 with corrected pharmacological group as Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use along with submission of fee of Rs. 7,500/- vide deposit slip# 9106510579
	Decision: Approved with innovator's specifications.	
236.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt Ltd. Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Detellix 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine……10mg
	Diary No. Date of R& I & fee	Dy. No. 13059 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Trintellix 10mg Tablet of Takeda Pharms USFDA Approved
	Me-too status	
	GMP status	The firm was rated Good as per GMp inspection dated 19.01.2022.
	Remarks of the Evaluator.	• Revise the pharmacological group from antipsychotic to antidepressants. • You have already adjusted the of weight of vortioxetine hydrobromide in master formula as per salt factor. Revise the label claim from vortioxetine..10mg to vortioxetine as hydrobromide..10mg. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit stability data as per zone IV-A.
	Decision: Deferred for following; • **Revision of the pharmacological group from antipsychotic to antidepressants.** • **Revision of the label claim as per reference product along with submission of applicable fee.** • **Addition of blistering and packing process in the manufacturing outlines.** • **Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.**	

<table>
<tr><td>237.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Zephyr Pharmatec Pvt Ltd. Plot No. A-39, S.I.T.E II, Super Highway, Karachi.</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Etexin CR 25mg Tablet</td></tr>
<tr><td></td><td>Composition</td><td>Each Extended Release Tablet Contains:
Paroxetine HCl eq to paroxetine……25mg</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy. No. 13060 dated 06.03.2019
Rs. 20,000/- dated 06.03.2019</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Antidepressant</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>The firm has claimed in-house specifications. Available in USP</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>30’s; As per SRO</td></tr>
<tr><td></td><td>Approval status of product in Reference Regulatory Authorities.</td><td>Paxil CR Tablet 25mg. USFDA approved.</td></tr>
<tr><td></td><td>Me-too status</td><td>Impika CR Tablet. Reg. No. 84447</td></tr>
<tr><td></td><td>GMP status</td><td>The firm was rated Good as per GMp inspection dated 19.01.2022.</td></tr>
<tr><td></td><td>Remarks of the Evaluator.</td><td>• Revised the pharmacological group from antipsychotic to antidepressants.
• The firm was asked to revise the composition, master formula, and manufacturing method in line with the submitted reference:.
<table>
<tr><th>Reference product</th><th>Action taken</th><th>Action required</th></tr>
<tr><td>Each extended-release tablet contains 12.5 mg, 25 mg, or 37.5 mg paroxetine equivalent to 14.25 mg, 28.51 mg, or 42.76 mg of paroxetine hydrochloride, respectively. The factor used is meant for hemihydrate form
.</td><td>The firm revised the quantity of API to 28.41mg.</td><td>Revision to 28.51mg is required.
Revise paroxetine as HCl to Paroxetine as HCl hemihydrate in the label claim.
Revise paroxetine as HCl to Paroxetine HCl hemihydrate in the master formula.</td></tr>
<tr><td>One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix</td><td>NIL</td><td>Revise the composition and manufacturing outlines.</td></tr>
<tr><td>In addition to controlling the rate of drug release in vivo, an enteric coat delays the start of drug release until tablets of PAXIL</td><td>NIL</td><td>Add enteric coating</td></tr>
</table></td></tr>
</table>

		CR have left the stomach. | | | • Added blistering and packing process in the manufacturing outlines. • Submitted Rs. 7500 fee (challan-9237480294).
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product along with submission of differential fee of 22,500/- fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
238.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Alfa-Zaf 0.5mcg Tablet
	Composition	Each Tablet Contains: Alfacalcidol ……..…0.5mcg
	Diary No. Date of R& I & fee	Dy. No. 12947 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	one alpha tablet 0.5 µg. PMDA Japan Approved
	Me-too status	Bon One Tablet 0.5mcg
	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020.
	Remarks of the Evaluator.	• The total weight of the tablet does not correspond to 630mg; however, it has been mentioned 630mg in the manufacturing outlines. Justification is required. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of 7500/- fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
239.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Amisul 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12948 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsycotic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	SOLIAN 50 amisulpride 50 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 50mg Tablet. Reg No. 76060
	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020.

	Remarks of the Evaluator.	• The total weight of the tablet does not correspond to 630mg; however, it has been mentioned 630mg in the manufacturing outlines. Justification is required. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with BP specifications. Registration letter will be issued after submission of fee of 7500/- fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
240.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lipizaf 200mg Capsule
	Composition	Each Capsule Contains: Fenofibrate (micronized)……200mg
	Diary No. Date of R& I & fee	Dy. No. 12945 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fenofibrate 200 mg capsules (micronized). MHRA approved
	Me-too status	Elmc 200mg Capsule. Reg No. 53499
	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020.
	Remarks of the Evaluator.	• Revise the pharmacological group to lipid modifying agents. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of fee of 7500/- fee for pre-registration for observed corrections/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
241.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Olanzaf 10mg Tablet
	Composition	Each Tablet Contains: Olanzapine……10mg
	Diary No. Date of R& I & fee	Dy. No. 12940 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Olanzapine 10mg Film-coated tablets. MHRA approved
	Me-too status	Olanzpine 10mg tablets. Reg. No. 81661
	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020.

	Remarks of the Evaluator.	• Revise the pharmacological group to antipsychotics. • Revise the label claim from each tablet contains to each film-coated tablet contains. • Revise 1.25kg of olanzapine to 0.25kg per 50,000 tablets as per exact calculation. • Add coating excipients in the composition and coating process in the manufacturing outlines. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product along with fee of 7500/- fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
242.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Olanzaf 5mg Tablet
	Composition	Each Tablet Contains: Olanzapine……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 12941 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Olanzapine 5mg Film-coated tablets. MHRA approved
	Me-too status	Olanzpine 5mg tablets. Reg. No. 81660
	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020.
	Remarks of the Evaluator.	• Revise the pharmacological group to antipsychotics. • Revise the label claim from each tablet contains to each film-coated tablet contains. • Revise 2.5kg per 50,000 tablets as per exact calculation. • Add coating excipients in the composition and coating process in the manufacturing outlines. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product along with fee of 7500/- fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
243.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Palidon 50mg Tablet
	Composition	Each Extended Released Film Coated Tablet Contains: Paliperidone……6mg
	Diary No. Date of R& I & fee	Dy. No. 12950 dated 06.03.2019

		Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	INVEGA (1.5mg, 3mg, 6mg, 9mg) Extended-Release Tablets USFDA approved
	Me-too status	Vegadon SR 6mg Tablets. Reg. No. 080372
	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020.
	Remarks of the Evaluator.	• Add blistering and packing process in the manufacturing outlines. • The reference product Invega, approved by USFDA is Extended release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. Provide evidence of required manufacturing technology as per reference product, and revise the manufacturing outlines accordingly. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for following: • **Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product.** • **Submit latest GMP certificate/last inspection report conducted within last three years.** • **Add blistering and packing process in the manufacturing outlines along with submission of applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
244.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Venlazaf 50mg Tablet
	Composition	Each Tablet Contains: Desvenlafaxine Succinate Eq. To Desvenlafaxine ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12944 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pristiq extended release tablets 50mg (film-coated). USFDA approved
	Me-too status	Denla XR 50mg Tablet. Reg. No. 70433 (Does not depict coating)
	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020. zfagmp
	Remarks of the Evaluator.	• You have claimed extended release film-coated tablet in the dosage form and specifications. Revise the label claim from "Each Tablet Contains" to extended release film-coated tablet contains". • Add blistering and packing process in the manufacturing outlines.

		• For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specification. Registration letter will be issued after submission of revised label claim as per reference product from "Each Tablet Contains" to extended release film-coated tablet contains along with full fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
245.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zafnil 16mg Tablet
	Composition	Each Tablet Contains: Betahistine as dihydrochloride……..…16mg
	Diary No. Date of R& I & fee	Dy. No. 12946 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Betahistine uncoated tablet 16mg. **MHRA** approved
	Me-too status	Vetinil 16mg Tablet. Reg. No. 40957
	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020.
	Remarks of the Evaluator.	• Revise the pharmacological group to Antivertigo preparations • Revise Betahistine as dihydrochloride…16mg to Betahistine dihydrochloride…16mg in the label claim. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with BP specification. Registration letter will be issued after submission of revised label claim, pharmacological group, manufacturing outlines as per reference product along with full fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
246.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zafpram 20mg Tablet
	Composition	Each film coated tablet contains: Escitalopram as oxalate……20mg
	Diary No. Date of R& I & fee	Dy. No. 12943 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant of SSRI class
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Escitalopram 20 mg film-coated tablets. MHRA approved
	Me-too status	Neolexa 20mg Tablet Reg. No. 66978

	GMP status	GMP certificate was issued based on inspection conducted on 29 october 2020.
	Remarks of the Evaluator.	• Adjust the weight of API in the master formula as per salt factor. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specification. Registration letter will be issued after submission of revised label claim, pharmacological group, manufacturing outlines as per reference product along with full fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
247.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zafta 1mg Tablet
	Composition	Each Tablet Contains: Cinitapride hydrogen tartrate eq. to cinitapride…1mg
	Diary No. Date of R& I & fee	Dy. No. 12942 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant of SSRI class
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cinitapride Cinfa 1 mg uncoated tablets (Spain Approved)
	Me-too status	Cidine 1mg tablet by highnoon laboratories
	GMP status	zfagmp
	Remarks of the Evaluator.	• Revise the pharmacological group to propulsives. • Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specification. Registration letter will be issued after submission of revised label claim, pharmacological group, manufacturing outlines as per reference product along with full fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
248.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Z-Loft 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Sertraline as HCl……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12951 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant of SSRI class
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lustral 50mg film coated tablets (**MHRA** Approved)
	Me-too status	Serglad Tablets 50mg. Reg. No. 30852
	GMP status	zfagmp

	Remarks of the Evaluator.	• Add blistering and packing process in the manufacturing outlines. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specification. Registration letter will be issued after submission of revised label claim, pharmacological group, manufacturing outlines as per reference product along with full fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
249.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Ameset 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron as HCl dihydrate……..…8mg
	Diary No. Date of R& I & fee	Dy. No. 12841 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antiemetics and antinauseants
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	12's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 8mg. Reg No. 82657
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• You have already adjusted the weight of API in the master formulation. Then, revised "Ondansetron as hydrochloride dihydrate" to Ondansetron hydrochloride dihydrate in master formulation. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product. Firm shall submit applicable fee for pre-approval change/correction of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
250.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Estapram 10mg Tablet
	Composition	Each film coated tablet Contains: Escitalopram as oxalate……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 12808 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant (SSRI)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Escitalopram 10 mg film-coated Tablets. **MHRA** approved
	Me-too status	Atcopram 10mg Tablets. Reg No. 48555
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• You have already mentioned film-coated tablet in the compostion. Revise the label claim in Form 5 to each film-coated tablet contains.

		• For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
251.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Fexofed 180mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl……..…180mg
	Diary No. Date of R& I & fee	Dy. No. 12810 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihistaminic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fexofenadine Hydrochloride 180 mg Film-coated tablets. MHRA approved
	Me-too status	Tilast Tablets 180mg. Reg No. 50251
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• You have already mentioned film-coated tablet in the compostion. Revise the label claim in Form 5 to each film-coated tablet contains. • For revision, submit applicable fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
252.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Histamer 16mg Tablet
	Composition	Each Tablet Contains: Betahistine Dihydrochloride……..…16mg
	Diary No. Date of R& I & fee	Dy. No. 12805 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antivertigo
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed BP specifications.
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Betahistine uncoated tablet 8mg. **MHRA** approved
	Me-too status	Vetinil 8mg Tablet. Reg. No. 40956
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
253.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore

<table>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Livamo 2mg Tablet</td></tr>
<tr><td></td><td>Composition</td><td>Each Film Coated Tablet Contains:
Pitavastatin as calcium……..…2mg</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy. No. 12825 dated 06.03.2019
Rs. 20,000/- dated 06.03.2019</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>HMG CoA reductase inhibitors</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>The firm has claimed in-house specifications. Available in JP</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>10’s; As per SRO</td></tr>
<tr><td></td><td>Approval status of product in Reference Regulatory Authorities.</td><td>Alipza▼ 2mg film-coated tablets. MHRA approved</td></tr>
<tr><td></td><td>Me-too status</td><td>Astin 2mg Tablet. Reg. No. 70448</td></tr>
<tr><td></td><td>GMP status</td><td>The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,</td></tr>
<tr><td></td><td>Remarks of the Evaluator.</td><td></td></tr>
<tr><td></td><td colspan="2">Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm’s application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as “M/s Ameer Pharma Pvt. Ltd.” decided to approve the product. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.</td></tr>
<tr><td>254.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Montac 10mg tablet</td></tr>
<tr><td></td><td>Composition</td><td>Each Film-coated Tablet Contains:
Montelukast as sodium……..…10mg</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy. No. 12825 dated 06.03.2019
Rs. 20,000/- dated 06.03.2019</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Antihistamininc (Leukotriene receptor antagonist)</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>The firm has claimed in-house specifications. Available in USP</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>10’s; As per SRO</td></tr>
<tr><td></td><td>Approval status of product in Reference Regulatory Authorities.</td><td>SINGULAIR® (montelukast sodium) film-coated tablets. USFDA approved</td></tr>
<tr><td></td><td>Me-too status</td><td>Singulair Tablets 10mg. Reg. No. 25259</td></tr>
<tr><td></td><td>GMP status</td><td>The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,</td></tr>
<tr><td></td><td>Remarks of the Evaluator.</td><td>• You have submitted the quantity of API for 300,000 tablets as
<table>
<tr><th>Raw material</th><th>Role</th><th>Specs</th><th>Quantity / tablet (mg)</th><th>Quantity batch (kg</th></tr>
<tr><td>Montelukast (as sodium)</td><td>API</td><td>BP</td><td>10.00</td><td>3.114</td></tr>
</table>
Revise the last column to 3kg.</td></tr>
<tr><td></td><td colspan="2">Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm’s application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as “M/s Ameer Pharma Pvt. Ltd.” decided to approve the product. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.</td></tr>
<tr><td>255.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>N Card 10mg Tablet</td></tr>
</table>

	Composition	Each Tablet Contains: Nebivolol as HCl ……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 12820 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Betablockers
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nebivolol 10 mg tablets. MHRA approved
	Me-too status	Byscard-10 Tablet. Reg. No. 71102
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	Submit GMP inspection report/ certificate.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with Innovator's specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
256.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Pantrop 40mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Pantoprazole as sodium sesquihydrate……..…40mg
	Diary No. Date of R& I & fee	Dy. No. 12845 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROTONIX (pantoprazole sodium) delayed-release tablets 40mg, for oral use. USFDA approved
	Me-too status	Qtum Tablet 40mg. Reg. No. 82648
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with USP specifcations. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
257.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Paratram 37.5/325mg Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol HCl……37.5mg Paracetamol……325mg
	Diary No. Date of R& I & fee	Dy. No. 12843 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed in-house specifications. Available in USP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms US-FDA approved
	Me-too status	Tril-P Tablet by Linta Pharmaceuticals. Reg. No. 78181
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Revise the pharmacological group to Opioids in combination with non-opioid analgesics.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with USP specifcations. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
258.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Ribamer 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Ribavirin……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 12826 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antivirals for treatment of HCV infections
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ribavirin 400 mg film-coated tablets. MHRA approved
	Me-too status	Orilan 400mg Tablet. Reg. No. 83292
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Revise the pharmacological group from antiviral to Antivirals for treatment of HCV infections.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
259.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Sitamer 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin HCl……1000mg Sitagliptin as phosphate monohydrate……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12829 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/1000mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/1000mg Tablets. Reg. No. 53100 (does not depict hydrate form).

	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Revise the pharmacological group to Combinations of oral blood glucose lowering drugs. • You have already adjusted theweight of API in the master formula as per salt factor. Revise Sitagliptin as phosphate monohydrate to Sitagliptin phosphate monohydrate in master formula. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of revised pharmacological group for the applied formulation along with submission of 7500/- fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
260.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Spasmer Tablet 80/80mg
	Composition	Each Film Coated Tablet Contains: Phlorglucinol hydrate……..…80mg Trimethylphloroglucinol……..…80mg
	Diary No. Date of R& I & fee	Dy. No. 12834 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specs.
	Pack size & Demanded Price	20's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PHLOROGLUCINOL / TRIMETHYLPHLOROGLUCINOL ACINO 62.233 mg / 80 mg, coated tablet. Approved by ANSM
	Me-too status	Despasm Tablet by Irza Pharmaceuticals. Reg. No. 85210
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Revise the pharmacological group to Drugs for functional gastrointestinal disorders • You have already mentioned Phlorglucinol hydrate in the label claim. Revise Phlorglucinol to Phlorglucinol hydrate in the composition / master formula • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with Innovator's specifcations. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
261.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Vastamer 20mg Tablet
	Composition	Each Tablet Contains: Atorvastatin as Calcium……20mg
	Diary No. Date of R& I & fee	Dy. No. 12805 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Hypo;ipidemic (HMG-CoA reductase inhibitor)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specs.
	Pack size & Demanded Price	10's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
	Me-too status	LIPITOR TABLETS 20MG. Reg. No. 23621
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• You have already adjusted the weight of API as per salt factor. The reference product in Health Canada contains Atorvastatin as calcium trihydrate. Revise the label claim from Atorvastatin as calcium to Atorvastatin as calcium trihydrate, and Atorvastatin calcium to Atorvastatin calcium trihydrate in the master formula. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product as per following label claim: **"Each film coated tablet contains:** **Atorvastatin as Calcium …… 20mg"** **Registration letter will be issued after submission of revised label claim as per reference product along with submission of full fee for pre-registration correction/changes fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
262.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Vilmet 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……..…50mg Metformin HCl……500mg
	Diary No. Date of R& I & fee	Dy. No. 12837 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	14's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/500 vildagliptin 50 mg/metformin hydrochloride 500 mg film coated tablet by Novartis Pharmaceuticals Australia Pty Ltd. **TGA** approved
	Me-too status	Galmet 50mg/500mg Tablet by Vision Pharma. Reg No. 81905
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The approved shelf-life of the product in 18 months in TGA Australia. You have claimed it as 2 years. Justify.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with Innovator's specifcations. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
263.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Ameerocaine Injection 5mg

	Composition	Each ml of 10ml and 20ml Contains: Bupivacaine ……5mg as Bupivacaine HCl
	Diary No. Date of R& I & fee	Dy. No. 12787 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Local anaesthetics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications
	Pack size & Demanded Price	5's (10ml), 5's (20ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bupivacaine 5 mg / mL Solution for injection (5ml, 10ml, 20ml). **TGA** approved
	Me-too status	Bucain Injection, 5mg/ml (20ml). Reg No. 39141 Bucan 0.5% Injection (10ml). Reg No. 39196
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Revise the label claim from "Each ml Of 10ml and 20ml Contains: Bupivacaine …5mg as Bupivacaine HCl" to "Each ml contains: Bupivacaine HCl as monohydrate …5mg". • You have applied for 10ml and 20ml. choose one filled volume. • Specify the ampoule material. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product as per following label claim: **"Each ml contains:** **Bupivacaine HCl as monohydrate …. 5mg"** **Registration letter will be issued after submission of full fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** **Registration Board further decided that firm shall choose one fill voume before issuance of registration letter.**	
264.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Atrameer Injection 25mg
	Composition	Each 2.5ml Ampoule Contains: Atracurium Besylate…25mg (eq. to atracurium 7.5mg/ml)
	Diary No. Date of R& I & fee	Dy. No. 12785 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Non-depolarising neuromuscular blocking agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications
	Pack size & Demanded Price	5's (2.5ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Atracurium Besilate 10 mg/ml Solution for Injection (2.5ml. 5ml, 25ml). MHRA approved
	Me-too status	Tracur Injection (2.5ml). Reg. No. 27350 Atramed Injection (2.5ml, 5ml). Reg. No. 28826
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Revise benzene sulfonic to benzene sulfonic acid in the composition. • Specify the ampoule material.

		• For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
265.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Dopamer 4% Injection
	Composition	Each 5ml Ampoule Contains: Dopamine hydrochloric acid……...200mg
	Diary No. Date of R& I & fee	Dy. No. 12790 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Adrenergic and dopaminergic agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dopamine 40 mg/ml Sterile Concentrate. (5ml). MHRA approved
	Me-too status	Dopna 200mg/5ml IV solution for infusion. Reg. No. 81455
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Revise the pharmacological group from beta-adrenergic agonist to Adrenergic and dopaminergic agents • In the label claim, revise the API from Dopamine hydrochloric acid to Dopamine hydrochloride. • Specify the ampoule material. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product as per following label claim: **"Each 5ml Ampoule Contains:** **Dopamine hydrochloric …….. 200mg"** **Registration letter will be issued after submission of full fee for pre-registration correction/changes of salt form of drug substace as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
266.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Fenatmer Injection 50ug
	Composition	Each ml Contains: Fentanyl…….50 mcg (as Fentanyl citrate)
	Diary No. Date of R& I & fee	Dy. No. 12792 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Opioid anesthetics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications
	Pack size & Demanded Price	25's (2ml), 10's (10ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fentanyl 50 micrograms/ml Solution for injection/Infusion (2ml,10ml). MHRA approved
	Me-too status	Fantol 100ug / 2ml Injection. Reg. No. 61050 Fantol 500ug / 10ml Injection. Reg. No. 61051

	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Specify the ampoule material. • You have applied for 2ml and 10ml. Choose one filled volume. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Submit approval of manufacturing facility for the applied drug product.
	Decision: Deferred for following; • **Evidence of approval of required manufacturing facility of "Liquid injection (Psychotropic section) from CLB.** • **Firm shall choose single fill volume along with submnission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
267.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Ltine Injection 1g
	Composition	Each 5ml Vial Contains: Levocarnitine……1g
	Diary No. Date of R& I & fee	Dy. No. 12794 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Aminoacid
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications
	Pack size & Demanded Price	5's (5ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Carnitor 1 g Solution for Injection (5ml). MHRA approved
	Me-too status	KEFEI INJECTION (Each vial contains: levocarnitine for injection...1.0g (amino-acid).. Reg. No. 59054; filled volume not specified
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• The international reference product is filled in 5 ml glass ampoule; you have applied for vial. Clarify. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Deferred for evidence of approval of required manufacturing facility of "Liquid Injectable vial" from CLB.	
268.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Meerocaine Injection 20mg
	Composition	Each 2ml Ampoule Contains: Lidocaine HCl……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 12795 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Local anaesthetics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications
	Pack size & Demanded Price	50's, 100's (2ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lidocaine 1% w/v injection (2ml, 5ml, 10ml, 20ml). MHRA approved
	Me-too status	L.A. Neutro Injection 20mg/2ml. Reg. No. 60495
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Specify the ampoule material.

		• For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product.	
269.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Muscomer Injection 4mg
	Composition	Each 2ml Ampoule Contains: Thiocolchicoside……4mg
	Diary No. Date of R& I & fee	Dy. No. 12800 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Local anaesthetics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1X5's, (2ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg/2 ml, solution injectable (IM) en ampoule. ANSM approved
	Me-too status	Thiolax Injection 4mg/2ml. Reg. No. 61919
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Specify the ampoule material. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with Innovator's specifcations. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
270.	Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Promer Injection 200mg/20ml
	Composition	Each 20ml Ampoule Contains: Propofol……200mg
	Diary No. Date of R& I & fee	Dy. No. 12799 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Local anaesthetics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1x5's, (2ml); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Propofol 1 % (10 mg/1 ml) Fresenius emulsion for injection or infusion (20ml ampoule, 50ml vial, 100ml vial). MHRA approved
	Me-too status	Thiolax Injection 4mg/2ml. Reg. No. 61919
	GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
	Remarks of the Evaluator.	• Specify the ampoule material. • The firm has mentioned emulsifier and oil phase in the composition. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that coveing letter of firm's application declared	

	full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product with BP specifcations. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
271.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Anzapine 10mg Tablet
	Composition	Each film coated tablet contains: Olanzapine ……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 11840 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Olanzapine 10mg Film-coated tablets. MHRA approved
	Me-too status	Olanzpine 10mg tablets. Reg. No. 81661
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • Submitted Rs. 7500 fee (challan-123202192)
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
272.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Anzapine 5mg Tablet
	Composition	Each film coated tablet contains: Olanzapine ……5mg
	Diary No. Date of R& I & fee	Dy. No. 11837 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Olanzapine 10mg Film-coated tablets. MHRA approved
	Me-too status	Olanzpine 10mg tablets. Reg. No. 81661
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • Submitted Rs. 7500 fee (challan-68074120735)
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
273.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Azepam 1mg Tablet

	Composition	Each Tablet Contains: Clonazepam ……..…1mg
	Diary No. Date of R& I & fee	Dy. No. 11898 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP, BP and JP
	Pack size & Demanded Price	10's, 20's, 14's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clonazepam Neuraxpharm 1 mg tablets. MHRA approved
	Me-too status	Curo 1mg Tablets. Reg. No. 65700
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-8248523475) • Submit proof of approval of manufacturing facility for the applied drug product. • Firm has provided letter No. F. 1-15/98-Lic (Vol-II) dated 26-06-2018 wherein additional section of Tablet Psychotropic section has been granted to M/s Perfect Pharma (Pvt.) Ltd. 5-Km, Manga Road, Raiwind, Lahore.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
274.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Azepam 2mg Tablet
	Composition	Each Tablet Contains: Clonazepam ……2mg
	Diary No. Date of R& I & fee	Dy. No. 11872 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP, BP and JP
	Pack size & Demanded Price	10's, 20's, 14's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clonazepam Neuraxpharm 2 mg tablets. MHRA approved
	Me-too status	Curo 1mg Tablets. Reg. No. 65698
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-468024002) • Submit proof of approval of manufacturing facility for the applied drug product • Firm has provided letter No. F. 1-15/98-Lic (Vol-II) dated 26-06-2018 wherein additional section of Tablet Psychotropic section has been granted to M/s Perfect Pharma (Pvt.) Ltd. 5-Km, Manga Road, Raiwind, Lahore.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
275.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cloze 100mg Tablet

	Composition	Each Film Coated Tablet Contains: Clozapine ……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 11838 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	10's, 20's, 14's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Denzapine ®100 mg Tablets. MHRA approved
	Me-too status	Clozcare Tablets 100mg. Reg. No. 84243
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm was asked revise the pharmacological group from dibenzodiazepine to Diazepines, oxazepines, thiazepines and oxepines. The firm revised it to diazapines. • Not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-52364567) • Revised the formulation from film-coated tablet to uncoated tablet. • Submit proof of approval of manufacturing facility for the applied drug product. **Revised label claim is as under;** **Each Tablet Contains:** **Clozapine ……..…100mg**
	Decision: Approved with USP specifications as per following label claim: **Each Tablet Contains:** **Clozapine ……..…100mg.**	
276.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cloze 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Clozapine ……..…25mg
	Diary No. Date of R& I & fee	Dy. No. 11875 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	10's, 20's, 14's, 30's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Denzapine ®25 mg Tablets. MHRA approved
	Me-too status	Clozcare Tablets 25mg. Reg. No. 84242
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm was asked revise the pharmacological group from dibenzodiazepine to Diazepines, oxazepines, thiazepines and oxepines. The firm revised it to diazapines. • Not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-65214216311) • Revised the formulation from film-coated tablet to uncoated tablet. • Submit proof of approval of manufacturing facility for the applied drug product **Revised label claim is as under;** • **Each Tablet Contains:** **Clozapine ……..…25mg**

	Decision: Approved with USP specifications as per following label claim: **Each Tablet Contains:** **Clozapine ……..…25mg.**	
277.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Factoline 500mg Tablet
	Composition	Each Tablet Contains: Citicoline Sodium eq to Citicoline ……..…500mg
	Diary No. Date of R& I & fee	Dy. No. 11836 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	10's, 20's, 14's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could be confirmed
	Me-too status	Cercolin Tablets 500mg. Reg. No. 48984
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revised the pharmacological group from central stimulants to psychostimulants. • Not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-67820021) • Mentioned ciprofloxacin HCl in the manufacturing outlines. Revised it. • Revised the formulation from uncoated tablet to film-coated tablet. • Coating composition still missing, but mentioned in the coating process. • The provided international reference product could not be verified. Provide proof international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
278.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kaldine 5mg Tablet
	Composition	Each Tablet Contains: Desloratadine ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 11848 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Histamine H1 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Desloratadine 5 mg Film-Coated Tablets. MHRA approved
	Me-too status	E-Din 5mg Tablets. Reg. No. 67986
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-71635780)

		• Revised the formulation from uncoated tablet to film-coated tablet. • Coating composition still missing, but mentioned in the coating process. **Revised label claim is as under;** **Each film coated Tablet Contains:** **Desloratadine ……..…5mg**
	Decision: Approved with USP specifications with relevant fee for specification.	
279.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalgil 50mg Tablet
	Composition	Each Tablet Contains: Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin…50mg
	Diary No. Date of R& I & fee	Dy. No. 11869 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitor
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sitagliptin 50 mg Film-coated Tablets. MHRA approved
	Me-too status	Bounty Tablets 50mg. Reg. No. 70189
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the composition with list and quantity of excipients. • You have applied for uncoated tablet, and have mentioned coating process in the manufacturing outlines. Clarify in line with the reference product. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim from uncoated tablet to coated tablets, complete composition with list and quantity of excipients with submission of 7500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
280.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalgil 50mg/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate Eq To Sitagliptin…50mg Metformin ……..…1000mg
	Diary No. Date of R& I & fee	Dy. No. 11893 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitor
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/1000mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/1000mg Tablets. Reg. No. 53100 (does not depict hydrate form).
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process.

		• Revised Metformin to Metformin HCl in the label claim and composition. • Submitted Rs. 7500 fee (challan-810940575) **Revised label claim is as under;** **Each Film Coated Tablet Contains:** **Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin……50mg** **Metformin HCl……..…1000mg.**
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of differential fee of 22,500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021	
281.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalgil 50mg/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate Eq To Sitagliptin…50mg Metformin……..…500mg
	Diary No. Date of R& I & fee	Dy. No. 11886 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitor
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/500mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/500mg Tablets. Reg. No. 53099 (does not depict hydrate form).
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • Revised Metformin to Metformin HCl in the label claim and composition. • Submitted Rs. 7500 fee (challan-24880958638) **Revised label claim is as under;** **Each Film Coated Tablet Contains:** **Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin……50mg** **Metformin HCl……..…500mg.**
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of differential fee of 22,500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
282.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalnor 4mg Tablet
	Composition	Each Tablet Contains: Lornoxicam ……..…4mg
	Diary No. Date of R& I & fee	Dy. No. 11895 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in BP
	Pack size & Demanded Price	5's, 10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 4 mg Film tabletten. Swiss Medic Approved

	Me-too status	Xoni-F 4mg Tablet. Reg. No. 76707
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Revised the formulation from uncoated tablet to film-coated tablet. • Coating composition still missing, but mentioned in the coating process. • Submitted Rs. 7500 fee (challan-52115931) **Revised label claim is as under;** **Each film coated Tablet Contains:** **Lornoxicam ……..…4mg**
	Decision: Approved with BP specifications with relevant fee for specification as per following label claim: **Each film coated Tablet Contains:** **Lornoxicam ……..…4mg**	
283.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalnor 8mg Tablet
	Composition	Each Tablet Contains: Lornoxicam ……..…8mg
	Diary No. Date of R& I & fee	Dy. No. 11858 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in BP
	Pack size & Demanded Price	10’s, 20’s, 30’s, 14’s, 100’s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi 8mg Tablet. Reg. No. 74933
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. Revised it. • Revised the formulation from uncoated tablet to film-coated tablet. • Coating composition still missing, but mentioned in the coating process. • Submitted Rs. 7500 fee (challan-8262000456) **Revised label claim is as under;** **Each film coated Tablet Contains:** **Lornoxicam ……..…8mg**
	Decision: Approved with BP specifications with relevant fee for specification as per following label claim: **Each film coated Tablet Contains:** **Lornoxicam ……..…8mg**	
284.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalpride 150mg Capsule
	Composition	Each Capsule Contains: Itopride HCl ……150mg
	Diary No. Date of R& I & fee	Dy. No. 11857 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Prokinetics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.

	Pack size & Demanded Price	10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Itoguard tablet 150mg. Reg. No. 076122
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Not submitted the composition with list and quantity of excipients. • Submitted Rs. 7500 fee (challan-766253593481) • Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
285.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalsart AVH Tablet 80/10/25mg
	Composition	Each Film Coated Tablet Contains: Valsartan ……80mg Amlodipine as besylate……..…10mg Hydrochlorothiazide……..…25mg
	Diary No. Date of R& I & fee	Dy. No. 11829 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Could not be confirmed.
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • In the BMR, mentioned amlodipine besiylate 10mg. then rivsed it to amlodipine as besylate…10mg, and amlodipine as besylate…. 1.38 kg. • Submitted Rs. 7500 fee (challan-766253593481) • Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board is required. • Proof of me-too product (same formulation and same strength) already registered in DRAP is required
	Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
286.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalsart AVH Tablet 160/10/25mg
	Composition	Each Film Coated Tablet Contains: Valsartan ……..…160mg

		Amlodipine as besylate……..……10mg Hydrochlorothiazide……25mg
	Diary No. Date of R& I & fee	Dy. No. 11832 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. US-FDA approved
	Me-too status	Exforge HCT 10/160/25MG film coated tablets by Novatris Pharma. Reg. No. 69551
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • In the BMR, mentioned amlodipine besiylate 10mg. then rivsed it to amlodipine as besylate…10mg,, and amlodipine as besylate…. 1.38 kg. • Submitted Rs. 7500 fee (challan-9686659941)
	Decision: Approved with USP specifications with relevant fee for specification.	
287.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalsart AVH Tablet 160/5/12.5mg
	Composition	Each Film Coated Tablet Contains: Valsartan ……..…160mg Amlodipine as besylate……5mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy. No. 11860 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets. **US-FDA** approved
	Me-too status	Exforge HCT 5/160/12.5MG film coated tablets. Reg. No. 69548
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • In the BMR, mentioned amlodipine besiylate 5mg. then rivsed it to amlodipine as besylate…5mg,, and amlodipine as besylate…. 0.69 kg. • Submitted Rs. 7500 fee (challan-782667195726)
	Decision: Approved with USP specifications with relevant fee for specification.	
288.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kalsart AVH Tablet 160/5/25mg
	Composition	Each Film Coated Tablet Contains: Valsartan……..…160mg

		Amlodipine as besylate……5mg Hydrochlorothiazide……..…25mg
	Diary No. Date of R& I & fee	Dy. No. 11882 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. US-FDA approved
	Me-too status	Exforge HCT 5/160/25MG film coated tablets by Novatris Pharma. Reg. No. 69549
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • In the BMR, mentioned amlodipine besiylate 5mg. then rivsed it to amlodipine as besylate…5mg, and amlodipine as besylate…. 0.69 kg. • Submitted Rs. 7500 fee (challan-5247712692)
	Decision: Approved with USP specifications with relevant fee for specification.	
289.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kart M 40/240mg Tablet
	Composition	Each Tablet Contains: Artemether……40mg Lumefantrine……..…240mg
	Diary No. Date of R& I & fee	Dy. No. 11897 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in IP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO Approved formulation.
	Me-too status	Malavel Tablets. Reg. No. 69818
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • Revised from uncoated tablet to film-coated tablet. • Submitted Rs. 7500 fee (challan-669251850594)
	Decision: Approved with IP specifications with relevant fee for specification.	
290.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kart M 80/480mg Tablet
	Composition	Each Tablet Contains: Artemether……80mg Lumefantrine……..…480mg
	Diary No. Date of R& I & fee	Dy. No. 11905 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019

	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in IP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO Approved formulation
	Me-too status	Eptrim-X 80/480mg Tablets. Reg. No. 75828
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-516284822614)
	Decision: Approved with IP specifications with relevant fee for specification.	
291.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kast 5mg Tablet
	Composition	Each Chewable Tablet Contains: Montelukast Sodium Eq. To Montelukast ……5mg
	Diary No. Date of R& I & fee	Dy. No. 11833 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Montelukat sodium chewable tablet. USFDA approved.
	Me-too status	Montekast 5mg Tablets. Reg. No. 79785
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Removed coating process in the manufacturing outlines. • Submitted Rs. 7500 fee (challan-67164576336)
	Decision: Approved with USP Specifications and correction in pharmacological group. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
292.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Katine 30mg Capsule
	Composition	Each Capsule Contains: Duloxetine as HCl……30mg
	Diary No. Date of R& I & fee	Dy. No. 11908 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dutor 30 mg gastro-resistant capsules, hard. **MHRA** approved
	Me-too status	Oxcym DR 30 mg Capsule. Reg. No. 53101
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the pharmacological group from SSRI antidepressant to antidepressant. • Revise the label claim from "each capsule contains; Duloxetine as HCl……60mg" to "Each gastro-

		resistant capsule contains: duloxetine hydrochloride enteric coated pellets eq. to duloxetine….30mg. • In the composition, you have mentioned Duloxetine HCl…6mg. Revise the quantity of API as per salt factor and strength of pellets in the master formula. • You have not submitted the list and quantity of excipients. • Provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission revise label claim as per reference product and differential fee of 30,000/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • **Firm will also submit revised master formula.** • **Firm will also submit source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. In case of imported source for the pellets, full fee for import registration shall also be submitted.**	
293.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Katine 60mg Capsule
	Composition	Each Capsule Contains: Duloxetine as HCl……..…60mg
	Diary No. Date of R& I & fee	Dy. No. 119881 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duloxetine 60 mg hard gastro-resistant capsules. **MHRA** approved
	Me-too status	Oxcym DR 60 mg Capsule. Reg. No. 53102
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revised the pharmacological group from SSRI antidepressant to antidepressant. • Revised the label claim from "each capsule contains: Duloxetine as Hcl…30mg" to "Each gastro-resistant capsule contains: duloxetine hydrochloride enteric coated pellets eq. to duloxetine….30mg. • Submitted Rs. 7500 fee (challan-43484467789) • Revise the quantity of API as per salt factor and strength of pellets in the master formula. • You have not submitted the list and quantity of excipients. • Provide the source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. **Revised label claim is as under;** **Each gastro-resistant capsule contains:** **Duloxetine hydrochloride enteric coated pellets eq. to duloxetine……F….60mg**
	Decision: Approved with USP specifications. Registration letter will be issued after submission of differential fee of 22,500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • **Firm will also submit revised master formula.**	

	• **Firm will also submit source of pellets along with GMP certificate of the firm, COA and stability summary sheets of three batches of the pellets. In case of imported source for the pellets, full fee for import registration shall also be submitted.**	
294.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kestec 20mg Tablet
	Composition	Each Tablet Contains: Ebastine ……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 119846 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Histamine H1 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in JP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bactil Forte 20 mg film-coated tablets. CIMA Approved.
	Me-too status	Ebist 20mg Tablets. Reg. No. 77854
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • Revised from uncoated tablet to film-coated tablet. • Submitted Rs. 7500 fee (challan-08007253149) **Revised label claim is as under;** **Each film coated tablet contains:** **Ebastine ……..…20mg**
	Decision: Approved with JP Specifications with relevant fee for specification as per following albel claim. **Each film coated tablet contains:** **Ebastine ……..…20mg**	
295.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Misart 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan ……20mg
	Diary No. Date of R& I & fee	Dy. No. 119892 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Angiotension receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and JP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan 20 mg tablets. MHRA Approved.
	Me-too status	Tecardic Tablets 20mg. Reg. No. 84799
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Removed coating process in the manufacturing outlines. • Submitted Rs. 7500 fee (challan-3415594469)
	Decision: Approved with USP specifications with relevant fee for specification.	
296.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan

	Brand Name +Dosage Form + Strength	Misart 40mg Tablet
	Composition	Each Tablet Contains: Telmisartan ……40mg
	Diary No. Date of R& I & fee	Dy. No. 119884 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Angiotension receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and JP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan 40 mg tablets. MHRA Approved.
	Me-too status	Tecardic Tablets 40mg. Reg. No. 84800
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Removed coating process in the manufacturing outlines. • Submitted Rs. 7500 fee (challan-369958408496)
	Decision: Approved with USP specifications with relevant fee for specification.	
297.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Misart 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan ……..…80mg
	Diary No. Date of R& I & fee	Dy. No. 119899 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Angiotension receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and JP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan 80 mg tablets. MHRA Approved.
	Me-too status	Tecardic Tablets 80mg. Reg. No. 84801
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Removed coating process in the manufacturing outlines. • Submitted Rs. 7500 fee (challan-531891473213)
	Decision: Approved with USP specifications with relevant fee for specification.	
298.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Misart-A 40/5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Amlodipine Besylate…...…5mg Telmisartan…….40mg
	Diary No. Date of R& I & fee	Dy. No. 11911 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TELMISARTAN/AMLO 40/5 telmisartan/amlodipine (as besilate) 40/5 mg tablet blister pack. TGA Approved.
	Me-too status	Ezitab-AM 4/5mg Tablet. Reg. No. 82041

	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Revised from film-coated tablet to uncoated tablet. • Submitted Rs. 7500 fee (challan-2620801791) **Revised label claim is as under;** **Each Tablet Contains:** **Amlodipine as Amlodipine Besylate…....…5mg** **Telmisartan…….40mg**
	Decision: Deferred for evidence of availability of bilayer compression machine along with revision of manufacturing outlone as per innovator product..	
299.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Moxcal 400mg Tablet
	Composition	Each Tablet Contains: Moxifloxacin HCl ……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 11866 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Moxifloxacin 400 mg film-coated tablets. Approved in MHRA.
	Me-too status	Navilox 400mg Tablet. Reg. No. 85166
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • The reference product in MHRA is film-coated tablet. You have applied for uncoated tablet. Clarify. • Revise Moxifloxacin HCl…400mg to Moxifloxacin as HCl…400mg, and adjust its weight in the master formula as per salt factor. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product with fee of 30,000/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
300.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Oxin 500mg Tablet
	Composition	Each Tablet Contains: Levofloxacin ……..…500mg
	Diary No. Date of R& I & fee	Dy. No. 11852 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and JP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levofloxacin (as hemihydrate) 500mg Film-coated Tablets. Approved in MHRA.
	Me-too status	Navilox 400mg Tablet. Reg. No. 85166
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.

	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • The firm applied for levofloxacin….500mg and mentioned levofloxacin hemihydrate in the manufacturing outlines. Revised the label claim to levofloxacin as hemihydrate……500mg. • Revised from uncoated tablet to film-coated tablet. • Submitted Rs. 7500 fee (challan-8668945913) **Revised label claim is as under;** **Each film coated Tablet Contains:** **Levofloxacin as hemihydrate ……500mg**
	Decision: Approved with USP specifications. Registration letter will be issued after submission of differential fee of 22,500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
301.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Oxycam 15mg Tablet
	Composition	Each Tablet Contains: Meloxicam……..…15mg
	Diary No. Date of R& I & fee	Dy. No. 11902 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meloxicam 15mg uncoated tablets. MHRA approved
	Me-too status	Melflam 15mg Tablets. Reg. No. 84266
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • You have applied for uncoated tablet. Remove the coating process form the manufacturing outlines. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of 7500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • **Firm will also submit revised manufacturing outlines with pre-registration variation fee.**	
302.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Percip 250mg Tablet
	Composition	Each Tablet Contains: Ciprofloxacin HCl……..…250mg
	Diary No. Date of R& I & fee	Dy. No. 11856 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ciprofloxacin 250 mg, film coated tablets. MHRA approved
	Me-too status	Decip Tablet 250mg. Reg. No. 84085

	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • The reference product in MHRA is film-coated tablet. You have applied for uncoated tablet. Clarify. • Revise Ciprofloxacin Hcl…250mg to Ciprofloxacin as Hcl…250mg, and adjust its weight in the master formula as per salt factor. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product and fee of 30,000/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
303.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Percip 500mg Tablet
	Composition	Each Tablet Contains: Ciprofloxacin HCl……500mg
	Diary No. Date of R& I & fee	Dy. No. 11865 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ciprofloxacin 500 mg, film coated tablets. MHRA approved
	Me-too status	Decip Tablet 500mg. Reg. No. 84086
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • Revised Ciprofloxacin Hcl…500mg to Ciprofloxacin as Hcl…500mg. • Revised from uncoated tablet to film-coated tablet. • Submitted Rs. 7500 fee (challan-453197838) **Revised label claim is as under;** **Each film coated Tablet Contains:** **Ciprofloxacin as HCl……500mg**
	Decision: Approved with USP specifications. Registration letter will be issued after submission of differential fee of 22,500/- for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
304.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Perfectine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine HCl……10mg
	Diary No. Date of R& I & fee	Dy. No. 11839 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Memantine hydrochloride 10 mg film-coated tablets. MHRA approved

	Me-too status	Cara-Tine 10 mg Tablets. Reg. No. 68529
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • Submitted Rs. 7500 fee (challan-1777043925)
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
305.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Perfectine 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine HCl……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 11879 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10’s, 20’s, 30’s, 14’s, 50’s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Memantine hydrochloride 20 mg film-coated tablets. MHRA approved
	Me-too status	Rement 20mg Tablet. Reg. No. 73884
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
306.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Perfectine 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine HCl ……5mg
	Diary No. Date of R& I & fee	Dy. No. 11842 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10’s, 20’s, 30’s, 14’s, 50’s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Memantine hydrochloride 5 mg film-coated tablets. MHRA approved
	Me-too status	Afdol 5mg Tablets. Reg. No. 47166
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Coating composition still missing, but mentioned in the coating process. • Submitted Rs. 7500 fee (challan-00569804)

	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
307.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Perfrizine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Cetirizine HCl……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 11847 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cetirizine Hydrochloride 10 mg film-coated tablets. MHRA approved
	Me-too status	Actilix-CTZ Tablets. Reg. No. 48644
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• The reference porudct has mentioned Cetirizine Hydrochloride in the brand and Cetirizine diydrochloride in the composition. The USP monograph for the drug substance has used formula cetirizine 2HCl and name as Cetirizine Hydrochloride. The same has been adopted by sigma-aldrich with CAS No, 83881-52-1. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product with submission of full fee for pre-registration correction/changes as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021and of list and quantity of excipients.	
308.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Peride 50mg Tablet
	Composition	Each Tablet Contains: Levosulpride ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 11850 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	LEVOPRAID® 50 mg Tablets by TEOFARMA Srl. Approved by AIFA
	Me-too status	Sulvo Tablets 50mg. Reg. No. 31748
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Application for the same product has already been submitted and processed vide Dy. No. 11891 dated 06.03.2019. Clarification is required. • Had not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-946812375083)
	Decision: Registration Board disposed of the application since same formulation has been approved in the name of firm in 317th meeting of Regsitration Board.	

309.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Permitine 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide……100mg
	Diary No. Date of R& I & fee	Dy. No. 11871 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Accord 100 mg film-coated tablets. MHRA approved.
	Me-too status	Lacolep 100mg Tablet. Reg. No. 73858
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
310.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Permitine 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide ……..…150mg
	Diary No. Date of R& I & fee	Dy. No. 11890 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Accord 150 mg film-coated tablets. MHRA approved.
	Me-too status	Lacolep 150mg Tablet. Reg. No. 73859
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
311.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Permitine 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 11841 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 50's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Lacosamide Accord 50 mg film-coated tablets. MHRA approved.
	Me-too status	Lacolep 50mg Tablet. Reg. No. 73857
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
312.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Paroxetine 25mg Tablet
	Composition	Each Enteric Film Coated controlled release Tablet Contains: Paroxetine As HCl……..…25mg
	Diary No. Date of R& I & fee	Dy. No. 11843 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paxil CR Tablet 25mg. USFDA approved.
	Me-too status	Impika CR Tablet. Reg. No. 84447
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the pharmacological group from selective serotonin and norepinephrine reuptake inhibitor to selective serotonin reuptake inhibitor. • You have not submitted the list and quantity of excipients. • You have submitted the reference wherein it is stated that: ➢ Each extended-release tablet contains 12.5 mg, 25 mg, or 37.5 mg paroxetine equivalent to 14.25 mg, 28.51 mg, or 42.76 mg of paroxetine hydrochloride, respectively. The factor used is meant for hemihydrate form. ➢ One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix. ➢ In addition to controlling the rate of drug release in vivo, an enteric coat delays the start of drug release until tablets of PAXIL CR have left the stomach. • Revise your composition, master formula, and manufacturing method in line with the above-mentioned facts. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Provide proof of availability of manufacturing facility.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500 for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
313.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Paroxetine 37.5mg Tablet
	Composition	Each Enteric Film Coated controlled release Tablet Contains: Paroxetine As Hcl…37.5mg
	Diary No. Date of R& I & fee	Dy. No. 11843 dated 06.03.2019

		Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paxil CR Tablet 37.5mg. USFDA approved.
	Me-too status	Peroxa CR 37.5 mg Tablet. Reg. No. 82148
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the pharmacological group from selective serotonin and norepinephrine reuptake inhibitor to selective serotonin reuptake inhibitor. • You have not submitted the list and quantity of excipients. • You have submitted incomplete manufacturing outlines. • You have submitted the reference wherein it is stated that: ➢ Each extended-release tablet contains 12.5 mg, 25 mg, or 37.5 mg paroxetine equivalent to 14.25 mg, 28.51 mg, or 42.76 mg of paroxetine hydrochloride, respectively. The factor used is meant for hemihydrate form. ➢ One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix. ➢ In addition to controlling the rate of drug release in vivo, an enteric coat delays the start of drug release until tablets of PAXIL CR have left the stomach. • Revise your composition, master formula, and manufacturing method in line with the above-mentioned facts. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021. • Provide proof of availability of manufacturing facility.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500 for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
314.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Plexine 20mg Capsule
	Composition	Each Capsule Contains: Fluoxetine as HCl……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 11909 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fluoxetine 20 mg capsules, hard. MHRA approved.
	Me-too status	Welflux 20mg Capsules. Reg. No. 64384
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Had submitted itopride HCl in the composition. Revised it. • Submitted Rs. 7500 fee (challan-335461239569)
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	

315.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Plexine 40mg Capsule
	Composition	Each Capsule Contains: Fluoxetine as HCl……..…40mg
	Diary No. Date of R& I & fee	Dy. No. 11885 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fluoxetine 40 mg capsules, hard. MHRA approved.
	Me-too status	Not confirmed
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Had not submitted the composition with list and quantity of excipients. Revised it. • Submitted Rs. 7500 fee (challan-80430745144)
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
316.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Pramper 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram As Oxalate ……10mg
	Diary No. Date of R& I & fee	Dy. No. 11870 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Escitalopram 10 mg film-coated tablets. MHRA approved
	Me-too status	Globoset 10mg Tablets. Reg. No. 36344
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of fee of Rs. 7,500 for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
317.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Pramper 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram As Oxalate ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 11859 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Escitalopram 5 mg film-coated tablets. MHRA approved
	Me-too status	Promital Tablet 5mg. Reg. No. 67846
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of fee of Rs. 7,500 for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
318.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Pre Cyc 20mg Tablet
	Composition	Each Tablet Contains: Piroxicam Beta cyclodextrin ……20mg
	Diary No. Date of R& I & fee	Dy. No. 11861 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	5's, 10's, 20's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CYCLADOL 20 mg scored tablet. **ANSM** approved
	Me-too status	Utrahit-beta Tablet. Reg. No. 81355
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • Revise Piroxicam Beta cyclodextrin…20mg to Piroxicam as beta cyclodextrin…20mg and adjust its weight in master formula as per equivalency factor. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of revised label claim as per reference product along with fee of Rs. 30,000 for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
319.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Prococal 500mcg Tablet
	Composition	Each Sugar Coated Tablet Contains: Mecobalamin ……..…500mcg
	Diary No. Date of R& I & fee	Dy. No. 11861 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in JP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Methicobide tablet 500 mcg sugar-coated, by Daito Corporation. Approved by **PMDA** Japan
	Me-too status	Balin 500mcg Tablet (sugar-coated) by Cibex Pharma Karachi. Reg. No. 74877
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients.

		• In the manufacturing outlines, you have mentioned risperidone… 50g, while at another place, clonazepam…0.2kg. revise it. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with JP specifications. Registration letter will be issued after submission of revised manufacturing outlines along with fee of Rs. 7500/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
320.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Quine 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate Eq. To Quetiapine…..…100mg
	Diary No. Date of R& I & fee	Dy. No. 11837 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Quetiapine 100mg film-coated tablets. MHRA Approved
	Me-too status	Qupixan Tablet 100 mg. Reg. No. 81961
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised manufacturing outlines along with fee of Rs. 7500/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
321.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Quine 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate Eq To Quetiapine ……25mg
	Diary No. Date of R& I & fee	Dy. No. 11832 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Quetiapine 25 mg film-coated tablets. MHRA approved
	Me-too status	Qupixan Tablet 25 mg. Reg. No. 81960
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised manufacturing outlines along with fee of Rs. 7500/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
322.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Quine XR 200mg Tablet

	Composition	Each Extended Release Tablet Contains: Quetiapine as fumarate……..…200mg
	Diary No. Date of R& I & fee	Dy. No. 11873 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alaquet XL 200 MG prolonged-release tablets. MHRA Approved
	Me-too status	Ziapine XR 200mg Oral Tablets. Reg. No. 78754
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. Please mention the sustained release polymer / excipient(s) as well. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
323.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Quine XR 150mg Tablet
	Composition	Each Extended Relase Tablet Contains: Quetiapine as fumarate ……150mg
	Diary No. Date of R& I & fee	Dy. No. 11904 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alaquet XL 150 MG prolonged-release tablets. MHRA Approved
	Me-too status	Ziapine XR 150mg Oral Tablets. Reg. No. 78755
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. Please mention the sustained release polymer / excipient(s) as well. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the master formulation of excipients as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
324.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ristol 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone……..…1mg
	Diary No. Date of R& I & fee	Dy. No. 11906 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Risperdal® 1mg film coated Tablets. **MHRA** approved
	Me-too status	Neo-Risp Tablet 1mg, film-coated. Reg No. 85184
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
325.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ristol 3mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone……3mg
	Diary No. Date of R& I & fee	Dy. No. 11894 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Risperdal® 3mg film coated Tablets. **MHRA** approved
	Me-too status	Neo-Risp Tablet 3mg, film-coated. Reg No. 85186
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
326.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ristol 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone……..…3mg
	Diary No. Date of R& I & fee	Dy. No. 11880 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Risperdal® 4mg film coated Tablets. **MHRA** approved
	Me-too status	Neo-Risp Tablet 4mg, film-coated. Reg No. 85187
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm has mentioned ristol 3mg in the bank challan, but corrected to ristol 4mg later. A separate challan has been provided for 3mg strength. • You have applied for risperidone…4mg on the cover letter, however, you have mentioned risperidone…3mg in the label claim and composition. Clarify. • You have not submitted the list and quantity of excipients.

		• For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim for Risperidone 4mg along with fee of Rs. 30,000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
327.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sart 160mg Tablet
	Composition	Each Tablet Contains: Valsartan ……..…160mg
	Diary No. Date of R& I & fee	Dy. No. 11889 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diovan tablets for oral administration (40 mg, 80 mg, 160 mg or 320 mg). USFDA approved Diovan film-coated tablets for oral administration (40 mg, 80 mg, 160 mg or 320 mg). TGA approved
	Me-too status	Nobel 160mg film-coated Tablets. Reg No. 71835
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the pharmacological group from Angiotensin II receptor antagonists to Angiotensin II receptor blockers. • You have not submitted the list and quantity of excipients. • You have mentioned uncoated tablet, but mention the coating process in the manufacturing outlines. The reference / innovator product in TGA is film-coated. Revise the label claim and submit coating composition. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product, revised pharmacological group along with fee of Rs. 7500/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
328.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sart 80mg Tablet
	Composition	Each Tablet Contains: Valsartan……..…80mg
	Diary No. Date of R& I & fee	Dy. No. 11853 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and JP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diovan tablets for oral administration (40 mg, 80 mg, 160 mg or 320 mg). USFDA approved Diovan film-coated tablets for oral administration (40 mg, 80 mg, 160 mg or 320 mg). TGA approved
	Me-too status	Nobel 80mg film-coated Tablets. Reg No. 71834
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the pharmacological group from Angiotensin II receptor antagonists to Angiotensin II receptor blockers. • You have not submitted the list and quantity of excipients.

		• You have mentioned uncoated tablet, but mention the coating process in the manufacturing outlines. The reference / innovator product in TGA is film-coated. Revise the label claim and submit coating composition. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product, revised pharmacological group along with fee of Rs. 7500/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
329.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sart A 160/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate As Amlodipine ……..…10mg Valsartan……..…160mg
	Diary No. Date of R& I & fee	Dy. No. 11830 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge tablets, film-coated (5/160 mg, 10/160 mg, 5/320 mg, and 10/320 mg). USFDA approved Exforge® 5 mg/80 mg film-coated tablets. MHRA approved.
	Me-too status	Amsart 10/160mg Tablet. Reg No. 84097
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the pharmacological group from Antihypertensives to Angiotensin II receptor blockers (ARBs) and calcium channel blockers. • Revise "Amlodipine Besylate As Amlodipine" in the label claim and compostion to "Amlodipine Besylate eq. to Amlodipine". • You have mentioned amlodipine in the manufacturing outlines. Revise it to amlodipine besylate and adjust its weight as per salt factor. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product, revised pharmacological group and manufacturing outlines along with fee of Rs. 30000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
330.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sart A 160/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate As Amlodipine ……5mg Valsartan……160mg
	Diary No. Date of R& I & fee	Dy. No. 11900 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP

	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge tablets, film-coated (5/160 mg, 10/160 mg, 5/320 mg, and 10/320 mg). USFDA approved Exforge® 5 mg/80 mg film-coated tablets. MHRA approved.
	Me-too status	Amsart 5/160mg Tablet. Reg No. 84098
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the pharmacological group from Antihypertensives to Angiotensin II receptor blockers (ARBs) and calcium channel blockers. • Revise "Amlodipine Besylate As Amlodipine" in the label claim and compostion to "Amlodipine Besylate eq. to Amlodipine". • You have mentioned amlodipine in the manufacturing outlines. Revise it to amlodipine besylate and adjust its weight as per salt factor. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product, revised pharmacological group and manufacturing outlines along with fee of Rs. 30000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
331.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sart A 80/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate As Amlodipine……5mg Valsartan……80mg
	Diary No. Date of R& I & fee	Dy. No. 11907 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge tablets, film-coated (5/160 mg, 10/160 mg, 5/320 mg, and 10/320 mg). USFDA approved Exforge® 5 mg/80 mg film-coated tablets. MHRA approved.
	Me-too status	Amsart 5/80mg Tablet. Reg No. 84099
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the pharmacological group from Antihypertensives to Angiotensin II receptor blockers (ARBs) and calcium channel blockers. • Revise "Amlodipine Besylate As Amlodipine" in the label claim and compostion to "Amlodipine Besylate eq. to Amlodipine". • You have mentioned amlodipine in the manufacturing outlines. Revise it to amlodipine besylate and adjust its weight as per salt factor. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product, revised pharmacological group and manufacturing outlines along with fee of Rs. 30000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	

332.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sova 20mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin Calcium……. …20mg
	Diary No. Date of R& I & fee	Dy. No. 11862 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Lipid lowering agent
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rosuvastatin 20 mg film-coated tablets. **MHRA** approved
	Me-too status	Rostor 20mg tablet. Reg. No. 74400
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the label claim to film-coated tablet. • Revise rosuvastatin to rosuvastain calcium in the master formula and adjust its weight as per salt factor. • Revise rosuvastatin calcium to rosuvastain as calcium in the label claim. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications as per following label claim: **Each film coated Tablet Contains:** **Rosuvastatin as Calcium……. …20mg.** **Registration letter will be issued after submission of revised label claim as per reference product, revised master formula with adjustment of weight as per salt factor along with fee of Rs. 30,000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.**	
333.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sova 5mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin Calcium ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 11849 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Lipid lowering agent
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's, 20's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rosuvastatin 5 mg film-coated tablets. **MHRA** approved
	Me-too status	Rostor 5mg tablet. Reg. No. 71183
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise the label claim to film-coated tablet. • Revise rosuvastatin to rosuvastatin calcium in the master formula and adjust its weight as per salt factor. • Revise rosuvastatin calcium to rosuvastatin as calcium in the label claim. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications as per following label claim:	

	Each film coated Tablet Contains: Rosuvastatin as Calcium……. …5mg. **Registration letter will be issued after submission of revised label claim as per reference product, revised master formula with adjustment of weight as per salt factor along with fee of Rs. 30,000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.**	
334.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Vol 10mg Tablet
	Composition	Each Tablet Contains: Nebivolol (hydrochloride)……10mg
	Diary No. Date of R& I & fee	Dy. No. 11878 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Betablocker
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP.
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nebivolol 10 mg tablets. MHRA approved
	Me-too status	Byscard-10 Tablet. Reg. No. 71102
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise Nebivolol (hydrochloride) to Nebivolol (as hydrochloride) in the label claim. • You have mentioned Nebivolol (hydrochloride) in the master formula; adjust its weight as per salt factor. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product, revised master formula with adjustment of weight as per salt factor along with fee of Rs. 30,000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
335.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Vol 2.5mg Tablet
	Composition	Each Tablet Contains: Nebivolol (hydrochloride)……2.5mg
	Diary No. Date of R& I & fee	Dy. No. 11901 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Betablocker
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nebivolol 2.5 mg tablets. MHRA approved
	Me-too status	Byscard-10 Tablet. Reg. No. 71104
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise Nebivolol (hydrochloride) to Nebivolol (as hydrochloride) in the label claim. • You have mentioned Nebivolol (hydrochloride) in the master formula; adjust its weight as per salt factor. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.

	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product, revised master formula along with fee of Rs. 30,000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
336.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Vol 5mg Tablet
	Composition	Each Tablet Contains: Nebivolol (hydrochloride)……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 11863 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Betablocker
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	5's, 10's, 30's, 14's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nebivolol 10 mg tablets. MHRA approved
	Me-too status	Byscard-10 Tablet. Reg. No. 71103
	GMP status	The firm was inspected on 22.09.2021 and 08.10.2021, where satisfactory level of GMP compliance was reported.
	Remarks of the Evaluator.	• Revise Nebivolol (hydrochloride) to Nebivolol (as hydrochloride) in the label claim. • You have mentioned Nebivolol (hydrochloride) in the master formula; adjust its weight as per salt factor. • You have not submitted the list and quantity of excipients. • For revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision: Approved with USP specifications. Registration letter will be issued after submission of revised label claim as per reference product, revised master formula along with fee of Rs. 30,000/- for correction/pre-approval change as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	

b. Deferred cases

The following cases were deferred by the registration Board in its 296th meeting to be considered on its turn.

337.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Lowvat-A 10/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate……..…10mg Amlodipine as besylate……..…10mg
	Diary No. Date of R & I & fee	Dy. No. 13527; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CADUET® (amlodipine as besylate and atorvastatin as calcium) tablets, film-coated. USFDA approved **Atorvastatin (mg)** 10 / 20 / 40 / 80 **Amlodipine (mg)** 2.5: X X X -- 5: X X X X 10: X X X X
	Me-too status	Corsafe AT 10/10 Tablets. Reg No. 68320
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021,

		without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
338.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Lowvat-A 20/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate……..…20mg Amlodipine as besylate……..…10mg
	Diary No. Date of R & I & fee	Dy. No. 13527; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CADUET® (amlodipine as besylate and atorvastatin as calcium) tablets, film-coated. USFDA approved **Amlodipine (mg)** / **Atorvastatin (mg)**: 2.5 (10: X, 20: X, 40: X, 80: --); 5 (X X X X); 10 (X X X X)
	Me-too status	Corsafe AT 10/20 Tablets. Reg No. 68321
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
339.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Lowvat-A 20/5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate……..…20mg Amlodipine as besylate……5mg
	Diary No. Date of R & I & fee	Dy. No. 13523; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CADUET® (amlodipine as besylate and atorvastatin as calcium) tablets, film-coated. USFDA approved **Amlodipine (mg)** / **Atorvastatin (mg)**: 2.5 (10: X, 20: X, 40: X, 80: --); 5 (X X X X); 10 (X X X X)
	Me-too status	Zodip Plus 20 Tablet. Reg No. 83294
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021,

		without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
340.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex 0.025% Cream
	Composition	Each Gram of Cream Contains: Fluocinolone Acetonide……..…0.25mg
	Diary No. Date of R & I & fee	Dy. No. 13562; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synlar Cream 0.025%. USFDA approved
	Me-too status	Dermolone Cream 0.025%. Reg. No. 41891
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications.	
341.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex C Cream
	Composition	Each Gram of Cream Contains: Fluocinolone Acetonide……..…0.25mg Clioquinol……3mg
	Diary No. Date of R & I & fee	Dy. No. 13557; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Clioquinol, combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synalar C Cream 0.025/3%. MHRA approved
	Me-too status	Synalar C Cream. Reg. No. 30866
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Deferred for the following; • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
342.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex C Ointment
	Composition	Each Gram of Ointment Contains: Fluocinolone Acetonide……0.25mg Clioquinol……..…3mg
	Diary No. Date of R & I & fee	Dy. No. 13556; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Clioquinol, combinations

	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synalar C Ointment 0.025/3%. MHRA approved
	Me-too status	Synalar C Ointment. Reg. No. 30865
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Deferred for the following; • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
343.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Univate 0.05% Cream
	Composition	Each Gram of Cream Contains: Halobetasol Propionate……..…0.5mg
	Diary No. Date of R & I & fee	Dy. No. 13546; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10g, 15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ultravate® (halobetasol propionate) Cream, 0.05%. USFDA approved
	Me-too status	Halovate Cream 0.05%. Reg. No. 46990.
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
344.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Univate 0.05% Ointment
	Composition	Each Gram of Ointment Contains: Halobetasol Propionate……0.5mg
	Diary No. Date of R & I & fee	Dy. No. 13547; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10g, 15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ultravate® (halobetasol propionate) Ointment, 0.05%. USFDA approved
	Me-too status	Halovate Ointment 0.05%. Reg. No. 46989
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.

	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
345.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Laxolol Sachet
	Composition	Each Sachet Contains: Macrogol……13.125g Sodium Chloride……..……0.3507g Sodium Hydrogen Carbonate……..…0.1785g Potassium Chloride……..…0.0466g
	Diary No. Date of R & I & fee	Dy. No. 13574; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Osmotic laxative
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Movicol 13.8g sachet, powder for oral solution. Approved by MHRA
	Me-too status	Forlax Sachet. Reg. No. 82099
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
346.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Mebis Sachet
	Composition	Each Sachet Contains: Mebevirine as HCl……..…135mg Ispaghula Husk……..…3.5mg
	Diary No. Date of R & I & fee	Dy. No. 13571; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Fybogel Mebeverine Granules for oral suspension Reckitt Benckiser Healthcare (UK) Limited, approved by MHRA, The firm has mentioned powder
	Me-too status	Mebsyl Sachet by Neutro Pharma (Pvt) Ltd., Lahore Reg. No. 74307
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	• Submit complete manufacturing outlines from dispensing to blistering. The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of revised label claim as per reference product along with fee of Rs. 30,000/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
347.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Maltomax-F Syrup

	Composition	Each 5ml Contains: Iron (III) Hydroxide Polymaltose Eq. to Elemental Iron……..…50mg Folic Acid…….0.35mg
	Diary No. Date of R & I & fee	Dy. No. 13552; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Iron in combination with folic acid
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Poly-F Syrup. Reg. No. 64045
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
348.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Clospo 100mg Soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Cyclosporine……..…100mg
	Diary No. Date of R & I & fee	Dy. No. 13566; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	NEORAL® Soft Gelatin 100mg Capsule. USFDA approved
	Me-too status	SANDIMMUN CAPSULES 100MG. Reg, No. 12176
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
349.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Clospo 50mg Soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Cyclosporine……..…50mg
	Diary No. Date of R & I & fee	Dy. No. 13567; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	NEORAL® Soft Gelatin 50mg Capsule. USFDA not discontinued or withdrawn for safety or efficacy reasons
	Me-too status	CYSPINRAL CAPSULES 50MG. Reg, No. 18272

	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
350.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Nidin 10mg Soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Nifedipine……10mg
	Diary No. Date of R & I & fee	Dy. No. 13569; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Dihydropyridine derivatives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Nifedipine soft capsules 10 mg. MHRA approved
	Me-too status	Nifedil Sg Capsule 10mg. Reg. No. 31291
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications.	
351.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Co-Ibtan 150/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan……..…150mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R & I & fee	Dy. No. 13531; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Irbesartan and diuretics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Avalide tablet 150mg/12.5mg, film-coated. USFDA approved
	Me-too status	Co- Irbisaff Tablet 150/12.5. Reg. No. 77191
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications.	
352.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Mefintin-EZ 80/480 mg Tablet
	Composition	Each Tablet Contains: Artemether……..…80mg Lumefantrine……..…480mg
	Diary No. Date of R & I & fee	Dy. No. 13527; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Artemisinin and derivatives, combinations
	Type of Form	Form 5

	Finished product Specification	IP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO Approved formulation
	Me-too status	Eptrim-X 80/480mg Tablets. Reg. No. 75828
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications.	
353.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	V Artan-S 97/103 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril……..…97mg Valsartan……..…103mg
	Diary No. Date of R & I & fee	Dy. No. 13533; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ENTRESTO™ (sacubitril and valsartan) 97/103mg tablets, film-coated. USFDA approved (with box warning)
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator	• Submit all the legal requirements meant for the product that requires the stability studies as per zone IV-A. • The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision; Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
354.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Irosid Injection (5ml)
	Composition	Each ml contains: Iron (III) Isomaltoside eq. to elemental Iron…100mg
	Diary No. Date of R & I & fee	Dy. No. 14946; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Iron, parenteral preparations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	5's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Monofer 100 mg/ml solution for injection/infusion (1ml, 2ml, 3ml, 5ml, 10ml ampule/vial). **MHRA** approved
	Me-too status	Wisofer Injection. Reg. No. 78521
	GMP status	

	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of revised label claim as per reference product along with fee of Rs. 30,000/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
355.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fonic Injection
	Composition	Each 2ml contains: Folinic acid (as calcium folinate)…15mg
	Diary No. Date of R & I & fee	Dy. No. 14949; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Folic acid analogs (not in ATC)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Calcium Folinate (eq to folinic acid) 7.5 mg/mL Injection (15mg/2ml). MHRA approved
	Me-too status	Could not be confirmed
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
356.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ronium Injection 50mg/5ml
	Composition	Each 5ml contains: Rocuronium Bromide…50mg
	Diary No. Date of R & I & fee	Dy. No. 14947; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Other quaternary ammonium compounds
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocuronium bromide 10 mg/ml solution for injection/infusion (**vial**). MHRA approved
	Me-too status	ESMERON INJECTION 50MG/5ML. Reg. No. 21154
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator	• The firm has claimed ampule packing. • The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	

357.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Saprin tablet
	Composition	Each film coated tablet contain: Amlodipine as besilate……..…5mg Valsartan……..…160mg
	Diary No. Date of R & I & fee	Dy. No. 14953; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 5/160. USFDA approved
	Me-too status	VALTAN -M 165 PLUS TABLET. Reg. No. 77206
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved. Registration letter will be issued after submission latest GMP certificate/last inspection report conducted within last three years.	
358.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Flunide Lotion 0.01% w/v
	Composition	Each ml of Lotion contains: Fluocinolone Acetonide…0.1%W/v
	Diary No. Date of R & I & fee	Dy. No. 14948; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications (available in USP as topical solution)
	Pack size & Demanded Price	60ml, 120ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator	• Had applied for lotion, but the composition in master formula are API in oily base. Justify • The firm submitted Derma-Smoothe/FS® fluocinolone acetonide Topical Oil, 0.01% approved in USFDA as reference product. • The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
359.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mebewin MR Capsule
	Composition	Each extended release capsule contains: Mebeverine HCl (pellets)……200mg

	Diary No. Date of R & I & fee	Dy. No. 14950; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	COLOFAC® MR 200mg Capsules. **MHRA** approved
	Me-too status	Mebrest-200 Capsule. Reg. No. 80547
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator	• The firm revised Mebeverine as HCl to Mebeverine HCl in the dossier. • The source of pellets is Vision Pharmaceuticals, Islamabad. • The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 30,000/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
360.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Hepa-Zerm Sachet
	Composition	Each Sachet contains: L-Ornithine-L-Asperate……..…3g
	Diary No. Date of R & I & fee	Dy. No. 14954; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Liver therapy mentioned as ornithine oxoglurate salt
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	5's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Hepa-Merz Sachet containing ornithine aspartate (granules for solution). **AGES** approved
	Me-too status	Lolar Sachet. Reg. No. 76499
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator	• The firm applied for powder for solution. The reference product is granules for solution. The firm revised the manufacturing outlines to granules. The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
361.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Opidol 100mg/2ml Injection
	Composition	Each 2ml ampule contains: Tramadol hydrochloride……..…100mg

	Diary No. Date of R & I & Fee	Dy No. 15610: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Other opioids
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	2mlx10's;, 2mlx30's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Tramadol 50mg/ml Solution for Injection or Infusion (2ml). MHRA approved
	Me-too Status	Welmadol Injection (2ml). Reg. No. 52629 (deos not show ampule or vial)
	GMP Status	The firm was inspected on 22.06.2020 with the following conclusion: In light of above the firm can be rated as complying GMP standards as per Schedule B-II of Drugs (LR&A) Rules, 1976. However, cGMP is a continual process of improvement for which the above stated points of improvement have been agreed upon by the management.
	Remarks of the Evaluator	•
	Pervious decision	The Board in its 289th meeting deferred the case for consideration on its turn as neither Narcotic or Psychotropic as per INCB
	Evaluation by PEC	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
362.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Nilbo 10mg/ml Injection
	Composition	Each ml contains: Nalbuphine hydrochloride……..….10mg
	Diary No. Date of R & I & Fee	Dy No. 15609: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Morphinan derivatives
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacture's specifications.
	Pack Size & Demanded Price	2x5 ampule PVC contour cellular package 1 contour cellular in a carton box.
	Approval Status of product in Reference Regulatory Authorities	NUBAIN (Nalbuphine Hydrochloride) Injection, 10 mg/mL (1ml ampule). Health Canada approved
	Me-too Status	Nalburax Injection. Reg. No. 28830 (deos not show ampule or vial)
	GMP Status	The firm was inspected on 22.06.2020 with the following conclusion: In light of above the firm can be rated as complying GMP standards as per Schedule B-II of Drugs (LR&A) Rules, 1976. However, cGMP is a continual process of improvement for which the above stated points of improvement have been agreed upon by the management.
	Remarks of the Evaluator	• Clarification is required about the pack size.

	Pervious decision	The Board in its 289th meeting deferred the case for consideration on its turn as neither Narcotic or Psychotropic as per INCB
	Evaluation by PEC	The case was evaluated before notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021, without considering the changes for fee as per the said notifications.
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021. • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	

Case no. 02 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

363.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Oxy LA 30% Injection IM
	Composition	Each ml Contains: Oxytetracycline HCl Eq. To Oxytetracycline……..300mg
	Diary No. Date of R& I & fee	Dy. No. 12778 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	100ml; decontrolled.
	Reference / Me-too status	Alamycin LA 300 mg/ml (as dihydrate) Solution for Injection (100ml, 250ml, 500ml amber color glass). HRPE approved.
	GMP status	The firm was inspected on 05-03-2018,17-08-2018 & 16-10-2018, where renewal of DML was recommended.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The reference product contains Magnesium Oxide, Dimethylacetamide, Sodium formaldehyde Sulphoxylate, Water for Injections
		• Revised the pharmacological group to Tetracyclines. • The mentioned excipients were not as per the reference product. Revised them. • As per the reference product mentioned above, the firm was asked to revise "Oxytetracycline HCl Eq. To Oxytetracycline…300mg" to "Oxytetracycline …300mg" The firm revised it to tetracycline and adjusted its weight in master formula. The firm submitted the reference (Reg. No. 52310) with label claim of Each ml contains Oxytetracycline as HCl…300mg • Lidocaine HCl is an API, which is not present in the reference product. The firm added it in the excipients. Removed it. • Submitted Rs. 30000 (challan-20699544116).
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	

364.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Oxy LA 30% Injection IM
	Composition	Each ml Contains: Oxytetracycline HCl Eq. To Oxytetracycline……..…300mg
	Diary No. Date of R& I & fee	Dy. No. 12777 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	50ml; decontrolled.
	Reference / Me-too status	Alamycin LA 300 mg/ml (as dihydrate) Solution for Injection (100ml, 250ml, 500ml amber color glass). HRPE approved.
	GMP status	The firm was inspected on 05-03-2018,17-08-2018 & 16-10-2018, where renewal of DML was recommended.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The reference product contains Magnesium Oxide, Dimethylacetamide, Sodium formaldehyde Sulphoxylate, Water for Injections.
		• Revised the pharmacological group to Tetracyclines. • The mentioned excipients are not as per the reference product. Revised them. • As per the reference product mentioned above, the firm was asked to revise "Oxytetracycline HCl Eq. To Oxytetracycline…300mg" to "Oxytetracycline …300mg" The firm revised it to tetracycline and adjusted its weight in master formula. The firm submitted the reference (Reg. No. 88833) with label claim of Each ml contains Oxytetracycline as Hcl…300mg (50ml) • Lidocaine HCl is an API, which is not present in the reference product. The firm added it in the excipients. Removed it. • Submitted Rs. 30000 (challan-54144206459)
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
365.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Vital 4 Solution
	Composition	Each 1000ml Contains: Vitamin A……..…30,000,000 IU Vitamin D3……..…1,000,000 IU Vitamin E……..…5,000mg Vitamin K3……6,000mg
	Diary No. Date of R& I & fee	Dy. No. 12782 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	500ml, 1000ml, 5000ml; decontrolled.
	Reference / Me-too status	Adekbar Oral Liquid. Reg. No. 73950

	GMP status	The firm was inspected on 05-03-2018,17-08-2018 & 16-10-2018, where renewal of DML was recommended.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Justify the capacity of one-liter water to accommodate Vitamin A…30,000,000 IU, Vitamin D3…1,000,000 IU, Vitamin E…5,000mg and Vitamin K3…6,000mg. the firm submitted the quantity to be Vitamin A…17.64g, Vitamin D3…25mg, Vitamin E…5,000mg and Vitamin K3…6,000mg • You have applied for solution. Justify the solubility of water insoluble vitamins in water. The firm submitted that these are emulsified with tween-80. • The quantity of APIs in master formula are not in line with the label claim. The firm revised the master formula accordingly. • Submitted Rs. (challan-70559611534)
	Decision: Deferred for following; • **Justification of applied strength of formulation considering the solubility of each drug substance in terms of mg/ml.** • **Justification for the proposing formulation of water insoluble vitamins in water.**	

Case no. 06 Registration applications of drugs submitted on Form 5F
a. Deferred cases

366.	Name, address of Applicant / Marketing Authorization Holder	M/s Cure Laboratories (Pvt.) Ltd. Plot # 11-12, Street # NS-2, National Industrial Estate, Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt.) Ltd. Plot # 11-12, Street # NS-2, National Industrial Estate, Rawat, Islamabad.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29080 Dated: 01/09/2021
	Details of fee submitted	PKR 30,000/- Dated: 05/07/2021
	The proposed proprietary name / brand name	CURAW 100MG SR CAPSULES
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Diclofenac sodium (as enteric coated pellets 32%)……100mg
	Pharmaceutical form of applied drug	Oral Capsules
	Pharmacotherapeutic Group of (API)	NSAIDS (Non-Steroidal Anti-Inflammatory Drugs)
	Reference to Finished product specifications	BP
	Proposed Pack size	1x10's & 1x20's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	DICLOMAX RETARD® (Diclofenac Sodium) 100mg Capsules MHRA APPROVED. Manufacturers: Almac Pharma Services Limited Almac House 20, Seagoe Industrial Estate, Craigavon, BT63, 5QD, UK Mipharm SpA Via Bernardo Quaranta, 12 20141-Milan, Italy.
	For generic drugs (me-too status)	Visodic SR 100mg Capsules Vision Pharmaceuticals (Pvt.) Ltd. (Reg.# 078171)
	GMP status of the Finished product manufacturer	Two additional sections granted by Licensing Division by Letter No. F-1-13/2017-Lic. Dated: 08th October 2020.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahutta Road, Islamabad, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its Validation/verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Diclofenac Sodium is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Stability Batches: (DE-322, DE-325, DE-329)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures as per BP and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Visodic 100mg SR Capsules by Vision Pharmaceuticals (Pvt.) Ltd. by performing quality tests (Description, Identification, Avg. Weight, Dissolution, and Assay, as per BP Monograph). CDP is with the Same Brand Visodic 100mg SR

		Capsules by Vision Pharmaceuticals (Pvt.) Ltd. at three pH Acid (1.2), Acetate Buffer (4.5) & Phosphate Buffer (6.8). and also the similarity factor (f2) is calculated
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial Triangle, Kahutta Road, Islamabad, Pakistan.		
API Lot No.	DE703ER		
Description of Pack (Container closure system)	White to off white colored, spherical, sustained release pellets filled in Natural/ Natural capsule shells of Size# 1.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12 (Months)		
Batch No.	C-013	C-014	C-015
Batch Size	720 Capsules	720 Capsules	720 Capsules
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	30-03-2020	30-03-2020	30-03-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Seven Products are approved in 307th Meeting of Registration Board with stability Data. Loxiten 20mg Capsules, Loxiten 30mg Capsules, Loxiten 60mg Capsules, Omexa 20mg Capsules, Omexa 40mg Capsules, Lansasure 15mg Capusles and Lansasure 30mg Capsules.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Vision Pharmaceuticals (Pvt.) Ltd. Semi Basic (000816) has a GMP Certificate No. 3-26/2019-Adl.Dir.(QA & LT-I) Dated: 25th February 2019. Valid Till: 10th February 2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The Material is locally purchased from Vision Pharmaceuticals (Pvt.) Ltd. Islamabad, Pakistan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

	Shortcomings	**Reply of the firm**
2.3.P.1	• You have claimed in-house specifications and have mentioned BP specifications in the stability	This was a typo mistake. It should be BP specifications. Correction is attached

	summary sheets. Justification is required. • You have mentioned the quantity per tablet. Justification is required. • The quantity of pellets per unit has been mentioned as 319mg. against 312.5mg. Justification is required. • You have not adjusted the potency of the pellets in the BMR. Justification is required.	This was a typo mistake. It should be BP specifications. Correction is attached The firm submitted that the calculation was based on 3% water content with potency adjustment. However, the water content in the COA of the firm is 4.1%.
	The dissolution testing method for pellets is not clear and not legible. Clarification is required.	The firm submitted the dissolution testing method of the pellets manufacturer, which does not contain acid resistance test as mentioned in the earlier submitted method.
3.2.S.4.3	• The drug product manufacturer shall submit their method validation protocol for the drug substance in section 3.2.S.4.3. • The specificity in the absence of impurity(es) shall be justified. • The drug substance (pellets) contains excipients. The ICH Q2 guidelines states that": "*Several methods for determining accuracy are available:* *a) application of the analytical procedure to synthetic mixtures of the drug product components to which known quantities of the drug substance to be analysed have been added;* *b) in cases where it is impossible to obtain samples of all drug product components, it may be acceptable either to add known quantities of the analyte to the drug product or to compare the results obtained from a second, well characterized procedure, the accuracy of which is stated and/or defined.*" • Justify the samples for accuracy (recovery) studies in the light of the above statement. The drug product manufacturer shall also clarify the term "placebo of diclofenac sodium capsules" used. • Moreover, the ICH Q2 guidelines states that "*the range of an analytical procedure is the interval between the upper and lower concentration (amounts) of analyte in the sample (including these concentrations) for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and linearity*". You have used different extremes for the precision, accuracy	Not submitted. It is true that specificity in the absence of impurities could not be justified. Mistakenly written as placebo, what I have done is crushed the pellets and added a known amount of API. Protocol/method of spiking is missing. The firm could not justify the same.

	and linearity parameters. Justification is required. • The ICH Q2 guidelines states "*the robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage*". Such variations include: - influence of variations of pH in a mobile phase; - influence of variations in mobile phase composition; - different columns (different lots and/or suppliers); - temperature; - flow rate; - change in wavelength of the detector You have tested six samples (each) of filtered and centrifuged solutions. Justification is required. • Typical variations to be studied for intermediate precision include days, analysts, equipment, etc. The use of an experimental design (matrix) is encouraged. The firm has submitted data of two analysts without considering other variations. Justification is required.	The firm used UV method, but did not test the effect of change of wavelength. Variation of equipment could not be followed as only single UV spectrophotometer is available.
3.2.S.4.5	Justifications of specifications for dissolution test for the drug substance shall be submitted.	We have claimed in-house specs and followed the method of pellets manufacturer.
3.2.P.2.2.1	• Submit the proof of procurement of the innovator product, i.e., Visodic 100mg capsules for CDP studies, and approval status of the product. • You have performed CDP on 06 capsules justification is required. • The acid retain test in dissolution test shall be clarified. • The WHO annexure 7 specifies that "For extended-release FPPs the time-points should be set to cover the entire duration of expected release, e.g. in addition to earlier time-points: samples at 1, 2, 3, 5 and 8 hours should be collected for a 12-hour release. You have conducted CDP for 2 h in phosphate buffer. Justification is required. • You have not mentioned the potency of the working standard in the calculation formula of percent drug release. • Submit the calculated similarity factor and all calculation thereof.	No data is available because it is a local purchase. We will be careful next time. The release at acid stage is almost negligible. we have used timepoint as adopted by pellets manufacturer. 100% potency was mentioned. Consider it as typo mistake. Not submitted.

	• The buffer has pH value of 7.2 in the CDP method, while it 6.8 in the results, Justification is required.	It is typo mistake consider it as 6.8
3.2.P.3.3	• The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. • A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified.	Not submitted. Not submitted
3.2.P.3.4	Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled.	Not submitted
3.2.P.4.2	Copies of analytical procedures of non-compendial excipient shall be submitted.	We did not use any excipient. The firm did not consider gelatin capsule as excipient.
3.2.P.4.3	Validation information for the analytical procedures for in-house standard excipients shall be submitted	In-house standard excipients were used.
3.2.P.4.4	Justification of specifications of the gelatin capsules is required.	The firm submitted the justification for specification as in-house.
3.2.P.4.5	For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE.	No animal or human origin excipients were used, the firm did not confirm the source of gelatin.
3.2.P.5.2	• The formula of assay and dissolution in terms of dilutions is not in line with the testing method. Clarification is required. • Water content test has not been performed. • The method for weight variation test has not been included in the testing method of the drug product. • The method for dissolution test has not been included in the testing method of the drug product	The firm did not justify the same. This is an un-official test. This is an un-official test We performed the testing as per BP specifications, which allows to adopt any suitable method. The dissolution test was performed as per pellets manufacturer specification.
3.2.P.5.6	• Justifications of specifications for dissolution test shall be submitted.	We performed the testing as per BP specifications, which allows to adopt any suitable method. The dissolution test was performed as per pellets manufacturer specification.
3.2.P.8	• Moreover, some values have been mentioned in the calculations, which are not clear w.r.t. the calculation formula. Clarification is required.	The firm again submitted the calculation, which could not be understood. It is pertinent to mention that the firm has used 900ml of dissolution medium, which is depicted in the calculation.

	• The potency of the working standard is 99.4%. Justify the 100% potency of the reference standard (having water content) used in the analyses. • You have not performed the impurity testing. You shall provide a discussion and justification for incomplete analyses of the drug product.	Not justified. We were unable to arrange the impurity standards. We requested the pellets manufacturer to arrange the same, who told they are working impurities and once it is complete they will provide all the data and standards.
	Submit audit trail report and record of digital data loggers	The firm submitted the record of temperature and humidity but did not submit audit trail report.
	The dissolution testing method has not been validated.	

S. No	Explanation / background	Previous decision (M-316): The case was deferred for:	Reply submitted
I.	The quantity of pellets per unit has been mentioned as 319mg. against 312.5mg. and potency of the pellets not adjusted in the BMR. Upon justification, the firm submitted that the calculation was based on 3% water content with potency adjustment. However, the water content in the COA of the firm is 4.1%.	Clarification of water content in the COA of the drug substance.	Initially we have performed Water Content Test on Karl Fisher at that time Karl Fisher was not performing well due to some technical error. Then we have sent the Karl Fisher for repairing to the supplier. When we received Karl Fisher after repairing we again performed Water Content test on 24-03-2020 before dispensing of Trial Batches for potency adjustment and we have adjusted potency of active material on the basis of this report. The copy of report is attached.
		Submission of calculation sheets.	Submitted
II.		Submission of audit trail record.	We have BP Monograph (Diclofenac Sodium Prolonged Release Capsules) for Testing of Curaw (Diclofenac Sodium) 100mg SR Capsules. The method for Assay and Dissolution mentioned in BP Monograph is on UV Spectrophotometer (BP Monograph attached). Therefore, there is no audit trail option

			available on our UV Spectrophotometer.
III.		Validation studies of dissolution testing method	Submitted with the same diffeicnecy as mentioned for assay validation.
IV.	The potency of the working standard used in all calculations is 99.4%. The firm was previously asked to justify the 100% potency of the reference standard (having water content) used in the analyses. Moreover, in a query related to dissolution method (as adopted from pellets manufacturer) for not mentioning the potency factor, the firm submitted for dissolution data 100% potency was mentioned. Consider it as typo mistake.	Justification of 100% potency of the working standard against 99.4% (having water content).	We have standardized the working standard supplied by the API Manufacturer internally and adjusted the potency of working standard as 100%.
V.	The water content test for drug product is not mentioned in the BP specification; however, it is a part of the pellet testing. Therefore, the firm was asked for this test for the capsules.	Justification for not performing the Water content test	We have applied BP monograph for the finished product (Curaw) analysis and the BP monograph does not show any water content test for the finished product. That's why we haven't performed water content test.
VI.	Method was not submitted previously	The method for weight variation test.	Submitted
VII.	The specificity in the absence of impurity(es) shall be justified. The firm previously submitted that It is true that specificity in the absence of impurities could not be justified.	Justification for specificity in the absence of impurities.	We are unable to arrange Impurity Standards form API Supplier. We have intimated Vision Pharmaceuticals to provide us impurity standards but they didn't provide the standards. Therefore, we have performed specificity without any impurity standards. We are requesting you to kindly consider this time we will be careful in future.
VIII.	The firm has used gelatin capsules	Certificate, confirming that the excipient(s) are free from BSE and TSE.	The capsule shell manufacturer did not provide the same. We will submit it before manufacturing of commercial batches,
IX.	The firm has used gelatin capsules	Halal certificate for gelatin.	Submitted
X.		Submission of details and proof of procurement of the	We are unable to arrange innovator product for Curaw

		innovator product for CDP studies.	100mg SR Capsules therefore we have performed CDP and Pharmaceutical Equivalence with Local Brand in Pakistan i.e. Visodic 100mg Capsules Manufactured by Vision Pharmaceuticals Islamabad. This product (Visodic 100mg Capsules) Registration # 078171, and is being manufactured by Vision Pharmaceuticals (Pvt.) Ltd. Model town Humak Islamabad. No procurement data available because it is a local purchase.
XI.	The firm did not submit clear calculations for CDP and the submitted data depicts that they did not perform CDP studies as per the ICH guidelines. They have tested the capsules separately at: i. pH 1.2 for 1 h; ii. pH 4.5 for 2 h and 8 h, and iii. pH 6.8 for 2 h and 8 h, and has applied formula for similarity factor on the combined data.		

Decision. Approved. Registration letter will be issued after submission of CDP results with the innovator drug product.

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

Case No. 01: Routine Registration applications of Human Drugs on Form 5F (Local)

367.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited., F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited., F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23846 dated 31/08/2021
	Details of fee submitted	PKR 75,000/-: dated 03/08/2021
	The proposed proprietary name / brand name	Bacetam 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Brivaracetam…….……25 mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Reference to Finished product specifications	**In house**
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BRIVIACT (10mg, 25mg, 50mg, 75mg, 100mg) tablets USFDA Approved
	For generic drugs (me-too status)	Brivatam 25mg tablet by M/s CCL Pharmaceuticals (Reg#109738)
	GMP status of the Finished product manufacturer	The firm has submitted GMP certificate issued on 13th august 2020 based on inspection conducted on 11th July 2019
	Name and address of API manufacturer.	Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related

		substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: ***Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months*** Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NP1713-1907002, NP1713-1908003, NP1713-1909004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product BRIVIACT 25mg Tablet of M/s UCB Pharma Ltd., 208 bath road, Slough, Berkshire, SL13WE, United Kingdom by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is BRIVIACT 25mg Tablet in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The CDP of Bacetam 25mg Tablet and BRIVIACT 25mg Tablet Show Equivalence. The % release of API in 15 minutes in all three mediums is more than 85%. Hence the drug product is categorized as very rapidly dissolving drug and there is no need to calculate F2 value.
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China.		
API Lot No.	NP1713-1908003		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	20PD-205	20PD-206	20PD-207
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Aug-2020	Aug-2020	Aug-2020
Date of Initiation	Sep-2020	Sep-2020	Sep-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Tapendol tablets 50mg, Tapendol tablets 75mg and Tapendol tablets 100mg. Inspection date: 11th March, 2019 The report shows that: The HPLC software is 21 CFR compliant. The firm has software for monitoring of stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 388b/17 issued by National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia issued on 17/Oct/2017 based on inspection conducted on 18-20 July 2017. ***(Validity three years)*** Firm has also submitted copy of DML No#Zhe20100526 of M/s Chengda Pharmaceuticals Co., Ltd., issued by Zhejiang Provincial Drug Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 i.e. License to import Raw material for manufacturing Trial Examination, test or Analysis for 2.5kg of drug substance Brivaracetam attested by AD (I&E) DRAP Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4	Submit latest GMP inspection report conducted with in last three years	The firm has submitted latest GMP inspection report. The firm was inspected on 07-05-2020 and conclusion of inspection was: Based on the area visited, documents/SOPs and system reviewed, commitment of the firm for continuous improvement and people met, it is concluded that the firm is operating at a Good level of GMP compliance.
1.6.5	Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	The firm have submitted written confirmation for active substance exported to EU to M/s Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China for Active substance Brivaracetam issued by Zhejiang Food and Drug Administration China confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.
3.2.S.4.2	The ratio of mobile phase used for assay of drug substance by drug product manufacturer (Mobile phase A; Phosphate Buffer 95: Acetonitrile	The firm submitted that we have used the same method as provided and used by the drug substance manufacturer but the way of writing is tabular form and mistakenly marked as gradient

	05 and mobile phase B; ACN) is different than that used by drug substance manufacturer (Phosphate Buffer 80: Acetonitrile 20), clarify? Furthermore, the drug substance manufacturer has followed isocratic elution while drug product manufacturer has followed gradient elution, clarify? •	elution instead of isocratic elution. ***However, the ratio of mobile phase is different from the drug substance manufacturer.***
3.2.P.6	Submit readable copy of COA of primary / secondary reference standard including source and lot number shall be provided.	The firm have submitted certificate of analysis of reference standard from M/s Chengda Pharmaceuticals Co., Ltd., China.
3.2.P.8	• Stability study at initial time point is not submitted • Submit Raw data sheets & analytical record for both assay & dissolution test containing detail of sample preparation, standard preparation and calculation formula for various performance parameters. • COA of API batch no. NP1713-1908003 is provided in batch analysis while in stability study batch no. NP1713-1908005 of API is mentioned, clarify which API was used in stability study • Submit readable copy of commercial invoice	• The firm have submitted stability study at initial time point • The firm have submitted submit Raw data sheets for both assay & dissolution test containing detail of sample preparation, standard preparation and calculation formula for various performance parameters. • The firm submitted that we have imported and used only one batch of API Brivaracetam having Batch No. NP1713-1908003 in the manufacturing of stability batches. It was a typographical error in stability protocol. • Firm has submitted readable copy of Commercial Invoice No: C05S05ZEP191224 Date: JAN 22, 2020 for 2.5kg of drug substance Brivaracetam attested by AD (I&E) DRAP Karachi on 28-02-2020

Time	Mobile phase A (%)	Mobile phase B (%)
0	80	20
15	80	20

Decision: Approved with innovators specifications.

- **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

368.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited., F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited., F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 23847 dated 31/08/2021
	Details of fee submitted	PKR 75,000/-: dated 03/08/2021
	The proposed proprietary name / brand name	Bacetam 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Brivaracetam…….……50 mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Reference to Finished product specifications	**In house**
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BRIVIACT (10mg, 25mg, 50mg, 75mg, 100mg) tablets USFDA Approved
	For generic drugs (me-too status)	Brivatam 50mg tablet by M/s CCL Pharmaceuticals (Reg#109739)
	GMP status of the Finished product manufacturer	The firm has submitted GMP certificate issued on 13th august 2020 based on inspection conducted on 11th July 2019
	Name and address of API manufacturer.	Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: ***Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months*** Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NP1713-1907002, NP1713-1908003, NP1713-1909004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product BRIVIACT 50mg

		Tablet of M/s UCB Pharma Ltd., 208 bath road, Slough, Berkshire, SL13WE, United Kingdom by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is BRIVIACT 50mg Tablet in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The CDP of Bacetam 50mg Tablet and BRIVIACT 50mg Tablet Show Equivalence. The % release of API in 15 minutes in all three mediums is more than 85%. Hence the drug product is categorized as very rapidly dissolving drug and there is no need to calculate F2 value.
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China.		
API Lot No.	NP1713-1908003		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	20PD-221	20PD-222	20PD-223
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Sep-2020	Sep-2020	Sep-2020
Date of Initiation	Sep-2020	Sep-2020	Sep-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Tapendol tablets 50mg, Tapendol tablets 75mg and Tapendol tablets 100mg. Inspection date: 11th March, 2019 The report shows that: The HPLC software is 21 CFR compliant. The firm has software for monitoring of stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 388b/17 issued by National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia issued on 17/Oct/2017 based on inspection conducted on 18-20 July 2017. ***(Validity three years)*** Firm has also submitted copy of DML No#Zhe20100526 of M/s Chengda Pharmaceuticals Co., Ltd., issued by Zhejiang Provincial Drug Administration.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 i.e. License to import Raw material for manufacturing Trial Examination, test or Analysis for 2.5kg of drug substance Brivaracetam attested by AD (I&E) DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4	Submit latest GMP inspection report conducted with in last three years	The firm has submitted latest GMP inspection report. The firm was inspected on 07-05-2020 and conclusion of inspection was: Based on the area visited, documents/SOPs and system reviewed, commitment of the firm for continuous improvement and people met, it is concluded that the firm is operating at a Good level of GMP compliance.
1.6.5	Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	The firm have submitted written confirmation for active substance exported to EU to M/s Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China for Active substance Brivaracetam issued by Zhejiang Food and Drug Administration China confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.
3.2.S.4.2	The ratio of mobile phase used for assay of drug substance by drug product manufacturer (Mobile phase A; Phosphate Buffer 95: Acetonitrile 05 and mobile phase B; ACN) is different than that used by drug substance manufacturer (Phosphate Buffer 80: Acetonitrile 20), clarify? Furthermore, the drug substance manufacturer has followed isocratic elution while drug product manufacturer has followed gradient elution, clarify? •	The firm submitted that we have used the same method as provided and used by the drug substance manufacturer but the way of writing is tabular form and mistakenly marked as gradient elution instead of isocratic elution. ***However, the ratio of mobile phase is different from the drug substance manufacturer.***
3.2.P.6	• Submit readable copy of COA of primary / secondary reference standard including source and lot number shall be provided.	The firm have submitted certificate of analysis of reference standard from M/s Chengda Pharmaceuticals Co., Ltd., China.
3.2.P.8	• Stability study at initial time point is not submitted	• The firm have submitted stability study at initial time point

Time	Mobile phase A (%)	Mobile phase B (%)
0	80	20
15	80	20

	• Submit Raw data sheets & analytical record for both assay & dissolution test containing detail of sample preparation, standard preparation and calculation formula for various performance parameters. • COA of API batch no. NP1713-1908003 is provided in batch analysis while in stability study batch no. NP1713-1908005 of API is mentioned, clarify which API was used in stability study • Submit readable copy of commercial invoice	• The firm have submitted Raw data sheets for both assay & dissolution test containing detail of sample preparation, standard preparation and calculation formula for various performance parameters. • The firm submitted that we have imported and used only one batch of API Brivaracetam having Batch No. NP1713-1908003 in the manufacturing of stability batches. It was a typographical error in stability protocol. • Firm has submitted readable copy of Commercial Invoice No: C05S05ZEP191224 Date: JAN 22, 2020 for 2.5kg of drug substance Brivaracetam attested by AD (I&E) DRAP Karachi on 28-02-2020

Decision: Approved with innovators specifications.

- **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

369.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited., F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited., F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23848 dated 31/08/2021
	Details of fee submitted	PKR 75,000/-: dated 03/08/2021
	The proposed proprietary name / brand name	Bacetam 75mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Brivaracetam…….……75 mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Reference to Finished product specifications	**In house**
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BRIVIACT (10mg, 25mg, 50mg, 75mg, 100mg) tablets USFDA Approved
	For generic drugs (me-too status)	Brivatam 75mg tablet by M/s CCL Pharmaceuticals (Reg#109740)

	GMP status of the Finished product manufacturer	The firm has submitted GMP certificate issued on 13th august 2020 based on inspection conducted on 11th July 2019
	Name and address of API manufacturer.	Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: ***Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months*** Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NP1713-1907002, NP1713-1908003, NP1713-1909004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product BRIVIACT 75mg Tablet of M/s UCB Pharma Ltd., 208 bath road, Slough, Berkshire, SL13WE, United Kingdom by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is BRIVIACT 75mg Tablet in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The CDP of Bacetam 75mg Tablet and BRIVIACT 75mg Tablet Show Equivalence. The % release of API in 15 minutes in all three mediums is more than 85%. Hence the drug product is categorized as very rapidly dissolving drug and there is no need to calculate F2 value.
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China.		
API Lot No.	NP1713-1908003		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	20PD-208	20PD-209	20PD-210
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Aug-2020	Aug-2020	Aug-2020
Date of Initiation	Sep-2020	Sep-2020	Sep-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Tapendol tablets 50mg, Tapendol tablets 75mg and Tapendol tablets 100mg. Inspection date: 11th March, 2019 The report shows that: The HPLC software is 21 CFR compliant. The firm has software for monitoring of stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 388b/17 issued by National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia issued on 17/Oct/2017 based on inspection conducted on 18-20 July 2017. ***(Validity three years)*** Firm has also submitted copy of DML No#Zhe20100526 of M/s Chengda Pharmaceuticals Co., Ltd., issued by Zhejiang Provincial Drug Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 i.e. License to import Raw material for manufacturing Trial Examination, test or Analysis for 2.5kg of drug substance Brivaracetam attested by AD (I&E) DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
Remarks of Evaluator [XI]:		
Decision: Approved with innovators specifications.		

• **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
370.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited., F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited., F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23849 dated 31/08/2021
	Details of fee submitted	PKR 75,000/-: dated 03/08/2021
	The proposed proprietary name / brand name	Bacetam 100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Brivaracetam…….……100 mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Reference to Finished product specifications	**In house**
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BRIVIACT (10mg, 25mg, 50mg, 75mg, 100mg) tablets USFDA Approved
	For generic drugs (me-too status)	Brivatam 100mg tablet by M/s CCL Pharmaceuticals (Reg#109741)
	GMP status of the Finished product manufacturer	The firm has submitted GMP certificate issued on 13th august 2020 based on inspection conducted on 11th July 2019
	Name and address of API manufacturer.	Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: ***Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months*** Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NP1713-1907002, NP1713-1908003, NP1713-1909004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product BRIVIACT 100mg Tablet of M/s UCB Pharma Ltd., 208 bath road, Slough, Berkshire, SL13WE, United Kingdom by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is BRIVIACT 100mg Tablet in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The CDP of Bacetam 100mg Tablet and BRIVIACT 100mg Tablet Show Equivalence. The % release of API in 15 minutes in all three mediums is more than 85%. Hence the drug product is categorized as very rapidly dissolving drug and there is no need to calculate F2 value.
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China.		
API Lot No.	NP1713-1908003		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	20PD-218	20PD-219	20PD-220
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Sep-2020	Sep-2020	Sep-2020
Date of Initiation	Sep-2020	Sep-2020	Sep-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Tapendol tablets 50mg, Tapendol tablets 75mg and Tapendol tablets 100mg. Inspection date: 11th March, 2019 The report shows that: The HPLC software is 21 CFR compliant. The firm has software for monitoring of stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 388b/17 issued by National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia issued on 17/Oct/2017 based on inspection conducted on 18-20 July 2017. ***(Validity three years)*** Firm has also submitted copy of DML No#Zhe20100526 of M/s Chengda Pharmaceuticals Co., Ltd., issued by Zhejiang Provincial Drug Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 i.e. License to import Raw material for manufacturing Trial Examination, test or Analysis for 2.5kg of drug substance Brivaracetam attested by AD (I&E) DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4	Submit latest GMP inspection report conducted with in last three years	The firm has submitted latest GMP inspection report. The firm was inspected on 07-05-2020 and conclusion of inspection was: Based on the area visited, documents/SOPs and system reviewed, commitment of the firm for continuous improvement and people met, it is concluded that the firm is operating at a Good level of GMP compliance.
1.6.5	Submit valid Good Manufacturing Practice (GMP) certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	The firm have submitted written confirmation for active substance exported to EU to M/s Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China for Active substance Brivaracetam issued by Zhejiang Food and Drug Administration China confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.
3.2.S.4.2	The ratio of mobile phase used for assay of drug substance by drug product manufacturer (Mobile phase A; Phosphate Buffer 95: Acetonitrile	The firm submitted that we have used the same method as provided and used by the drug substance manufacturer but the way of writing is tabular form and mistakenly marked as gradient

<table>
<tr><td></td><td>05 and mobile phase B; ACN) is different than that used by drug substance manufacturer (Phosphate Buffer 80: Acetonitrile 20), clarify? Furthermore, the drug substance manufacturer has followed isocratic elution while drug product manufacturer has followed gradient elution, clarify?
<table><tr><td>Time</td><td>Mobile phase A (%)</td><td>Mobile phase B (%)</td></tr><tr><td>0</td><td>80</td><td>20</td></tr><tr><td>15</td><td>80</td><td>20</td></tr></table></td><td>elution instead of isocratic elution. However, the ratio of mobile phase is different from the drug substance manufacturer.</td></tr>
<tr><td>3.2.P.6</td><td>Submit readable copy of COA of primary / secondary reference standard including source and lot number shall be provided.</td><td>The firm have submitted certificate of analysis of reference standard from M/s Chengda Pharmaceuticals Co., Ltd., China.</td></tr>
<tr><td>3.2.P.8</td><td>• Stability study at initial time point is not submitted
• Submit Raw data sheets & analytical record for both assay & dissolution test containing detail of sample preparation, standard preparation and calculation formula for various performance parameters.
• COA of API batch no. NP1713-1908003 is provided in batch analysis while in stability study batch no. NP1713-1908005 of API is mentioned, clarify which API was used in stability study
• Submit readable copy of commercial invoice</td><td>• The firm have submitted stability study at initial time point
• The firm have submitted Raw data sheets for both assay & dissolution test containing detail of sample preparation, standard preparation and calculation formula for various performance parameters.
• The firm submitted that we have imported and used only one batch of API Brivaracetam having Batch No. NP1713-1908003 in the manufacturing of stability batches. It was a typographical error in stability protocol.
• Firm has submitted readable copy of Commercial Invoice No: C05S05ZEP191224 Date: JAN 22, 2020 for 2.5kg of drug substance Brivaracetam attested by AD (I&E) DRAP Karachi on 28-02-2020</td></tr>
</table>

Decision: Approved with innovators specifications.

- **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

371.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals., 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals., 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25932 dated: 17-09-2021
	Details of fee submitted	PKR 30,000/-: 02-09-2021 (deposit slip # 977318003814)
	The proposed proprietary name / brand name	**Monticel Sachet 4mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Montelukast (as Sodium)……4mg
	Pharmaceutical form of applied drug	Powder for Oral use
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	BP specification
	Proposed Pack size	14's and 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Singulair (4mg) oral granules USFDA Approved
	For generic drugs (me-too status)	Myteka 4mg Sachet by M/s Hilton Pharma (Reg#039695)
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on 06-07-2020, based on inspection conducted on 09-06-2020
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China 317016
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of API as per zone IV-A conditions Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (11001-161001, 11001-161002, 11001-161003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence and comparative dissolution study against the comparator product i.e. Myteka Sachet 4mg by M/s Hilton Pharma. Pharmaceutical Equivalence have been conducted by performing quality tests (Assay, Dissolution and Uniformity of dosage form). Results of CDP studies have been submitted against the same brand in Pharmacopoeial Media (0.5% SLS) only. Release of both the test and reference product is more than 85% in hence no calculation of f2 factor is required.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product including specificity, accuracy, and precision.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China 317016		
API Lot No.	11001-201005		
Description of Pack (Container closure system)	Alu – Foil Sachet, packed in carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	300 Sachet	500 Sachet	500 Sachet
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	15-04-2021	20-04-2021	20-04-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., issued by China Food and Drug Administration valid till 14-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice No#TYI21009 dated 29-12-2020 for import of 60kg of Montelukast Sodium attested by AD (I&E) DRAP Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time)

Remarks of Evaluator [XI]:

Section	Observations	Response
3.2.S.4	• Drug substance manufacturer has stated USP specifications while drug product manufacturer has stated USP/BP specifications, clarify? • Analytical procedure of drug substance by drug substance manufacturer shall be submitted • You have mentioned the use of Montelukast sodium working standard in analytical procedure during preparation of standard solution while pharmacopeia states the use of montelukast dicyclohexylamine reference standard, clarify?	• Analytical method and specifications of montelukast sodium in both pharmacopeia (BP/USP) are same, therefore both standards are mentioned on COA. Evidence is submitted. • Firm has submitted analytical procedure of drug substance by provided drug substance manufacturer • ***The firm submitted that montelukast sodium is readily available as raw material and used as working standard in routine testing after standardization against montelukast dicyclohexylamine (reference standard).***
3.2.S.5	Reference standard is montelukast dicyclohexylamine while working standard is montelukast sodium, clarify?	***Montelukast sodium (working standard) is used in routine testing, which is standardized against montelukast dicyclohexylamine (reference standard).***
3.2.P.2.1	• Clarification is required since the innovator product contain magnesium stearate in addition to other excipients while the applied product does not contain magnesium stearate. • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product? • The results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 shall be submitted and discussed	• The firm submitted that magnesium stearate is routinely used as lubricant in oral solid dosage form to improve flow characteristics of the product. ***The drug product is fine granular powder having satisfactory flow characteristics without the use of magnesium stearate. Moreover, addition of magnesium stearate causes haziness in solution prepared after reconstitution as observed in product development phase. That is why, the said excipient was not used.*** • Firm submitted that Pharmaceutical equivalence of the applied product has been performed against comparator product as per DRAP's guidance document (FAQs about form 5F) dated 28-01-21. • The firm submitted that comparative dissolution profile has been conducted in three BCS media (pH 1.2, 4.5 &6.8) and already submitted pharmacopeial method (0.5% SLS) & already submitted. ***Montelukast sodium did not show any response in the stated BCS media across physiological range (pH 1.2, 4.5 & 6.8) therefore it was not applicable to calculate similarity factor in those media (firm has submitted a few chromatograms for evidence). However, in pharmacopeial method both products showed more than 85% dissolution, therefore no calculation was required.***
3.2.P.3.2	The reference formulation states granules for oral suspension for applied formulation. Clarification is required in manufacturing process and process control whether granules will be prepared in-house or otherwise.	The firm submitted that the applied formulation is free flowing granular powder and is completely soluble after reconstitution for use. API is geometrically mixed with other excipients.

3.2.P.5	• You have mentioned the use of Montelukast sodium working standard in analytical procedure during preparation of standard solution while pharmacopeia states the use of montelukast dicyclohexylamine reference standard, clarify?	***The firm submitted that montelukast sodium is readily available as raw material and used as working standard in routine testing after standardization against montelukast dicyclohexylamine (reference standard).***
3.2.P.6	Reference standard is montelukast dicyclohexylamine while working standard is montelukast sodium, clarify?	***Montelukast sodium (working standard) is used in routine testing, which is standardized against montelukast dicyclohexylamine (reference standard).***
3.2.P.8	• Submit 6th month stability study data at both real time and accelerated conditions • Submit readable copy of commercial invoice • Compliance Record of HPLC software 21CFR shall be submitted • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)	• Firm has submitted 6th month stability study data at both real time and accelerated conditions • Firm has submitted readable copy of commercial invoice • The firm has submitted Compliance Record of HPLC software 21CFR • Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)

Decision: Deferred for Scientific justification for use of Montelukast sodium as reference standard in analytical procedures instead of Montelukast dicyclohexylamine specified by BP monograph.

Section	Observations	Response
1.3.4	Submit latest GMP inspection report conducted with in last three years	The firm has submitted latest GMP inspection report. The firm was inspected on 07-05-2020 and conclusion of inspection was: Based on the area visited, documents/SOPs and system reviewed, commitment of the firm for continuous improvement and people met, it is concluded that the firm is operating at a Good level of GMP compliance.
1.6.5	Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	The firm have submitted written confirmation for active substance exported to EU to M/s Chengda Pharmaceuticals Co., Ltd., No. 36, Huanghe Road, Huimin Subdistrict, Jiashan, Zhejiang, China for Active substance Brivaracetam issued by Zhejiang Food and Drug Administration China confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.
3.2.S.4.2	The ratio of mobile phase used for assay of drug substance by drug product manufacturer (Mobile phase A; Phosphate Buffer 95: Acetonitrile 05 and mobile phase B; ACN) is different than that used by drug substance manufacturer (Phosphate Buffer 80: Acetonitrile 20), clarify? Furthermore, the drug substance manufacturer has followed isocratic elution while drug product manufacturer has followed gradient elution, clarify?	The firm submitted that we have used the same method as provided and used by the drug substance manufacturer but the way of writing is tabular form and mistakenly marked as gradient elution instead of isocratic elution. ***However, the ratio of mobile phase is different from the drug substance manufacturer.***

Time	Mobile phase A (%)	Mobile phase B (%)
0	80	20

	• 15 | 80 | 20	
3.2.P.6	Submit readable copy of COA of primary / secondary reference standard including source and lot number shall be provided.	The firm have submitted certificate of analysis of reference standard from M/s Chengda Pharmaceuticals Co., Ltd., China.
3.2.P.8	• Stability study at initial time point is not submitted • Submit Raw data sheets & analytical record for both assay & dissolution test containing detail of sample preparation, standard preparation and calculation formula for various performance parameters. • COA of API batch no. NP1713-1908003 is provided in batch analysis while in stability study batch no. NP1713-1908005 of API is mentioned, clarify which API was used in stability study • Submit readable copy of commercial invoice	• The firm have submitted stability study at initial time point • The firm have submitted Raw data sheets for both assay & dissolution test containing detail of sample preparation, standard preparation and calculation formula for various performance parameters. • The firm submitted that we have imported and used only one batch of API Brivaracetam having Batch No. NP1713-1908003 in the manufacturing of stability batches. It was a typographical error in stability protocol. • Firm has submitted readable copy of Commercial Invoice No: C05S05ZEP191224 Date: JAN 22, 2020 for 2.5kg of drug substance Brivaracetam attested by AD (I&E) DRAP Karachi on 28-02-2020

372.	Name, address of Applicant / Marketing Authorization Holder	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Name, address of Manufacturing site.	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26524 dated 24/09/2021
	Details of fee submitted	PKR 20,000/-: dated 28/12/2020 PKR 10,000/-: dated 09/06/2021
	The proposed proprietary name / brand name	Dexopra Capsule 30mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole (as dual delayed release pellets) ……..……. 30 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	**Innovator's Specifications"**
	Proposed Pack size	3x10, s capsules
	Proposed unit price	MRP Rs. 540/-
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 30 mg by M/s The Searle Company Ltd. (Reg#086978)

	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 22-03-2019 based on inspection conducted on 01-03-2019
	Name and address of API manufacturer.	**Source of Pellets:** Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DLP125T, DLP124T, DLP123T)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Dextop 30mg capsule by M/s The Searle Company Ltd Karachi by performing quality tests (Assay, Dissolution).
	Analytical method validation/verification of product	Firm have submitted method verification studies including linearity, range, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	Source of Pellets: Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com		
API Lot No.	DLP 420		
Description of Pack (Container closure system)	Alu-alu Blisters, packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	T-003	***T-004***	***T-005***
Batch Size	5000 caps	***3000 caps***	***3000 caps***

Manufacturing Date	06-2019	***12/10/2021***	***15/10/2021***
Date of Initiation	27-06-2019		
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice #502094 dated 19-02-2019 for 1.2kg of Dexlansoprazole DDR Pellets 22.5% batch # DLP420 from Vision Pharmaceuticals Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of one batch only along with chromatograms, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time.

Remarks of Evaluator [XI]:

Section	Observations	Response
	• Submit valid DML as the submitted DML has been expired on 24-11-2021 • Submit latest GMP inspection report conducted with in last three years • Submit valid GMP certificate of drug substance manufacturer	• The firm have submitted valid copy of DML issued in name of M/s Magns Pharmaceuticals on 06/06/2022 • The firm have submitted GMP certificate issued on 13-04-2022 based on inspection conducted on 11-03-2022. • The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted Batch Manufacturing Record (BMR) for all the batches (T-003, T-004, T-005) of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>. ***Two more batches, Batch T-004 and T-005 was manufactured on 12/10/2021 and 15/10/2021 respectively while batch T-003 was manufactured on23/06/2019. The details of these two batches are incorporated in above table.***
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• ***Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is not submitted.*** • ***Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is not submitted.***

3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product. • Comparative dissolution profile against the innovator product shall be submitted	• ***No clarification is submitted. However pharmaceutical equivalence is again submitted. Test like content uniformity, loss on drying and identification are not performed.*** • ***The firm submitted that we have performed comparative study for assay and dissolution hence Comparative dissolution profile is not required***
3.2.P.4	• Justify the use of gelatine capsule shell in dexlansoprazole capsule since innovator product has specified hypromellose capsule shells. • For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE. • Halal certificate for gelatin shall be provided	• The firm submitted that hard gelatine capsules are easily available and having same dissolving time and behaviour and other competitors are also using gelatine capsule shell. • ***No clarification submitted*** • The firm have submitted Halal certificate for gelatin shall
3.2.P.5	• You have mentioned innovator specifications under section 1.5.6 while you have followed manufacturer specifications for applied product, justify? • The tests of content uniformity and loss on drying were not included in the submitted specifications as recommended by literature of innovator product, justify? • Results of specificity test in method validation is not submitted • The copies of complete analysis of at least two batches shall be provided while you have provided batch analysis of only one batch, justify?	• The firm submitted that we have followed innovator's specifications. • ***The firm submitted that content uniformity test is recommended for dosage form which have API 25mg or less than 25mg in all pharmacopeia reference, so we have not performed.*** • ***Results of specificity test in method validation is not submitted*** • Firm have submitted copies of complete analysis of two batches
3.2.P.8	• Submit latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) • Submit Raw data sheets & analytical record of stability studies containing calculation formula for both assay & dissolution test • Justify why you have submitted stability study data of only one batch while it is required to submit stability study data of three batches as per zone IV-A conditions • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)	• ***Inspection report for exemption conducted by the panel for authenticity of stability data (PSI) is not submitted*** • ***Firm has not submitted stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.*** • ***Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted***

Decision: Deferred for following:

- **Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer**
- **Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)**
- **Submission of Comparative dissolution profile against the innovator product**
- **Submission of results of specificity test in method validation studies of drug product**

• **Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.** • **Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)**		
373.	Name, address of Applicant / Marketing Authorization Holder	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Name, address of Manufacturing site.	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26525 dated 24/09/2021
	Details of fee submitted	PKR 20,000/-: dated 28/12/2020 PKR 10,000/-: dated 09/06/2021
	The proposed proprietary name / brand name	Dexopra Capsule 60mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole (as dual delayed release pellets) ……..…… 60 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	**Innovator's Specifications"**
	Proposed Pack size	3x10, s capsules
	Proposed unit price	MRP Rs. 840/-
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 60 mg by M/s The Searle Company Ltd. (Reg#086979)
	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 22-03-2019 based on inspection conducted on 01-03-2019
	Name and address of API manufacturer.	**Source of Pellets:** Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DLP125T, DLP124T, DLP123T)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Dextop 60mg capsule by M/s The Searle Company Ltd Karachi by performing quality tests (Assay, Dissolution).
	Analytical method validation/verification of product	Firm have submitted method verification studies including linearity, range, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	Source of Pellets: Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com		
API Lot No.	DLP 420		
Description of Pack (Container closure system)	Alu-alu Blisters, packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	T-003	***T-004***	***T-005***
Batch Size	3000 caps	***3000 caps***	***3000 caps***
Manufacturing Date	06-2019	***12/10/2021***	***15/10/2021***
Date of Initiation	27-06-2019		
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of one batch only along with chromatograms, COA and summary data sheets.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time.

Remarks of Evaluator [XI]:

Section	Observations	Response
	• Submit valid DML as the submitted DML has been expired on 24-11-2021 • Submit latest GMP inspection report conducted with in last three years • Submit valid GMP certificate of drug substance manufacturer	• The firm have submitted valid copy of DML issued in name of M/s Magns Pharmaceuticals on 06/06/2022 • The firm have submitted GMP certificate issued on 13-04-2022 based on inspection conducted on 11-03-2022. • The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted Batch Manufacturing Record (BMR) for all the batches (T-003, T-004, T-005) of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>. ***Two more batches, Batch T-004 and T-005 was manufactured on 12/10/2021 and 15/10/2021 respectively while batch T-003 was manufactured on23/06/2019. The details of these two batches are incorporated in above table.***
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• ***Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is not submitted.*** • ***Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is not submitted.***
3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product. • Comparative dissolution profile against the innovator product shall be submitted	• ***No clarification is submitted. However pharmaceutical equivalence is again submitted. Test like content uniformity, loss on drying and identification are not performed.*** • ***The firm submitted that we have performed comparative study for assay and dissolution hence Comparative dissolution profile is not required***
3.2.P.4	• Justify the use of gelatine capsule shell in dexlansoprazole capsule since innovator product has specified hypromellose capsule shells. • For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE. • Halal certificate for gelatin shall be provided	• The firm submitted that hard gelatine capsules are easily available and having same dissolving time and behaviour and other competitors are also using gelatine capsule shell. • ***No clarification submitted*** • The firm have submitted Halal certificate for gelatin shall

3.2.P.5	• You have mentioned innovator specifications under section 1.5.6 while you have followed manufacturer specifications for applied product, justify? • The tests of content uniformity and loss on drying were not included in the submitted specifications as recommended by literature of innovator product, justify? • Results of specificity test in method validation is not submitted • The copies of complete analysis of at least two batches shall be provided while you have provided batch analysis of only one batch, justify?	• The firm submitted that we have followed innovator's specifications. • ***The firm submitted that content uniformity test is recommended for dosage form which have API 25mg or less than 25mg in all pharmacopeia reference, so we have not performed.*** • ***Results of specificity test in method validation is not submitted*** • Firm have submitted copies of complete analysis of two batches
3.2.P.8	• Submit latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) • Submit Raw data sheets & analytical record of stability studies containing calculation formula for both assay & dissolution test • Justify why you have submitted stability study data of only one batch while it is required to submit stability study data of three batches as per zone IV-A conditions • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Submit documents for the procurement of API	• ***Inspection report for exemption conducted by the panel for authenticity of stability data (PSI) is not submitted*** • ***Firm has not submitted stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.*** • ***Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted*** • The firm has submitted copy of invoice #800742 dated 23-09-2021 for 2.5kg of Dexlansoprazole DDR Pellets 22.5% batch # DLP775 from Vision Pharmaceuticals Islamabad.

Decision: Deferred for following:

- **Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer**
- **Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)**
- **Submission of Comparative dissolution profile against the innovator product**
- **Submission of results of specificity test in method validation studies of drug product**
- **Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.**
- **Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)**

374.	Name, address of Applicant / Marketing Authorization Holder	M/s Jaskan Pharmaceuticals (Pvt.) Ltd., Plot No. 50 Sunder Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceuticals (Pvt.) Ltd., Plot No. 50 Sunder Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24360 dated: 03-09-2021
	Details of fee submitted	PKR 30,000/-: 18-06-2021 (deposit slip # 85552371641)
	The proposed proprietary name / brand name	Clarkan Dry Suspension 250mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Clarithromycin ……. 250mg
	Pharmaceutical form of applied drug	Dry powder for oral suspension
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotic
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Klaricid Paediatric Suspension 250mg/5ml MHRA Approved
	For generic drugs (me-too status)	Klaricid DS Granules by M/s Abbot Laboratories Limited (Reg#076148)
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on 18-02-2021, based on inspection conducted on 26-10-2020
	Name and address of API manufacturer.	Source of Micro-Pellets: Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of API as per zone IV-A conditions Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (CTM0511, CTM0510, CTM0513)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence against the Klaricid DS 250mg/5ml by M/s Abbot

		Laboratories by performing quality tests (Appearance, Identification, pH, Assay).
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product including specificity, accuracy and precision.

STABILITY STUDY DATA

Manufacturer of API	Source of Micro-Pellets: Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591		
API Lot No.	CTM-0645		
Description of Pack (Container closure system)	Glass bottle 90ml packed in paper board U/C box		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	CJ-01	CJ-02	CJ-03
Batch Size	33 bottles	33 bottles	
Manufacturing Date	04-03-2020	04-03-2020	04-03-2020
Date of Initiation	05-03-2020	05-03-2020	05-03-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not required as local source was used.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	Submit valid GMP certificate of drug substance manufacturer	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing	• The firm have submitted Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /

	of the Drug substance / Active Pharmaceutical ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Active Pharmaceutical ingredient by Drug Product manufacturer according to USP monograph. ***However, the number and limits of tests and analytical procedure are different from the drug substance manufacturer as monograph for clarithromycin EC Taste Mask Pellets are not available in USP.*** • Firm have submitted Analytical Method Verification studies including accuracy and repeatability (method precision) performed by the Drug Product manufacturer. ***However, results of specificity is not submitted.***
3.2.P.2	• Justification is required why Antimicrobial Preservatives were included in composition of applied product although no antimicrobial preservative is included in composition of innovator product • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph (uniformity of dosage unit, deliverable volume, loss on drying)	• ***The firm submitted that we have used these three preservatives (Sodium benzoate, Methyl parabene sodium, Propyl parabene sodium) in very small quantity to get their synergistic preservative effect. They further sated that they may omit parabens from formulation for commercial batches.*** • The firm submitted that comparative study along with uniformity of dosage unit, deliverable volume and loss on drying has been performed and submitted
3.2.P.4	No data / document is submitted in this section	Relevant data / document is submitted in this section
3.2.P.5	• Justification is required why specification does not include complete testing as recommended by USP monograph (uniformity of dosage unit, deliverable volume, loss on drying)	• The firm submitted that complete testing as recommended by USP monograph (uniformity of dosage unit, deliverable volume, loss on drying) has been done
3.2.P.6	No data / document is submitted in this section	COA's of Drug substance has been submitted instead of primary / secondary reference standard
3.2.P.8	• Preservative content and efficacy test not performed during stability study, clarify? • In use stability study of reconstitution suspension shall be submitted • Submit documents for the procurement of API • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	• Preservative content and efficacy test has been performed and submitted • In use stability study of reconstitution suspension has been performed and submitted. However, the limits of pH test are not within recommended limit range after 14 days. (Limit 4---5.4……result 3.81) • The firm has submitted copy of invoice #602776 dated 02-03-2020 for 10kg of Clarithromycin Taste Masked Micro Pellets 27.5% batch # CTM0645 from Vision Pharmaceuticals Islamabad. • The firm submitted that EZ Chrom software is 21 CFR compliant and submit audit trail reports on product testing

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued upon submission of following:**

	a. Specification, Analytical procedure & Analytical record for drug substance analysis by Jaskan Pharmaceuticals (Pvt.) Ltd., Plot No. 50 Sunder Industrial Estate Lahore along with for the drug substance analysis. **b. Performance of specificity parameter for analytical method verification studies of drug substance shall be submitted.** **c. Results of specificity test in analytical method verification studies for drug substance.** **d. Submission of In use stability study of 14 days for reconstituted suspension**	
375.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Ltd, B-18, S.I.T.E, Karachi.
	Name, address of Manufacturing site.	M/s Atco Laboratories Ltd, B-18, S.I.T.E, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25529 dated 14/09/2021
	Details of fee submitted	PKR 30,000/-: dated 15/06/2021 PKR 120,000/-: dated 26/07/2021 (balance fee) Total PKR 150,000/-: (Imported Pellets Fee)
	The proposed proprietary name / brand name	Dexlansoprazole DR Capsule 30mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole MS 30mg (as enteric coated pellets)
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	In house
	Proposed Pack size	7s, 10s, 14s, 20s, 28s & 30s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Delanzo DR Capsule 30mg by M/s SAMI Pharmaceuticals (Reg# 089145)
	GMP status of the Finished product manufacturer	The firm was inspected on 28-02-2017 for renewal of DML and conclusion of inspection was: Keeping in view good facilities provided for manufacturing and quality control of pharmaceutical products registered in the name of firm being produced at site the overall good maintenance of plant and the required documentation and standards operating procedures were also found to be in place, the panel recommended the grant of renewal of Drug Manufacturing License No. 000188 (Formulation) of the firm.
	Name and address of API manufacturer.	**Source of Pellets:** Alphamed Formulations Pvt., Limited Survey No.225, Sampanbole Village, Shamirpet Mandal, Medchal Malkajgiri District Telangana - 500 101, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (AJ2A7004, AJ2A7005, AJ2A7006)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product that is Dexilant 30mg Capsule by Takeda Pharmaceuticals America, Inc by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Source of Pellets: Alphamed Formulations Pvt., Limited., Survey No.225, Sampanbole Village, Shamirpet Mandal, Medchal Malkajgiri District Telangana - 500 101, India		
API Lot No.	AJ4A0003/B, RD-0050-023, RD-0050-024		
Description of Pack (Container closure system)	Alu-alu Blisters, packed in printed carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	AU231B	AU232B	AU233B
Batch Size	22500 caps	22500 caps	22500 caps
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	12-2020	12-2020	12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of Rofl 500mcg tablet on the basis of which Registration Board in its 277th meeting dated 27-29 December, 2017 decided to approve registration of Rofl 500mcg tablet.

		Inspection date: 10-10-2017 The report shows that: The HPLC software is 21 CFR compliant. Adequate monitoring and control are available for stability chambers
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP issued by Drug Control Administration, Government of Telangana India valid till 29/08/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted two copies of invoice confirming the import of 6kg and 9kg dexlansoprazole dual delayed release pellets respectively attested by AD (I&E) DRAP Karachi. Invoice # and date, supplier and receiver details are not clearly readable
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator [XI]:

Section	Observations	Response
	Submit latest GMP inspection report conducted with in last three years	The firm has submitted cGMP certificate issued on 24-12-2020 base on inspection conducted on 06th November 2020
1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit shall be clearly mentioned indicating the type and concentration of pellets	The have submitted label claim as under: Each capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5% w/w eq. to Dexlansoprazole: 30mg
3.2.S.4	• Justification is required for not including the test for Percentage of enantiomer in specification by drug substance manufacturer and drug product manufacturer although stated by the innovator product? (drug is racemic mixture) • Justify the dissolution specification set by the drug substance manufacturer (0.1N HCl, Buffer pH 6 and Buffer pH 7.4) since they are different from the innovator dissolution specifications (0.1N HCl, pH 5.5 and pH 6.75). • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Enantiomer is the process related impurity of pure API manufacturing of Dexlansoprazole and well controlled in drug substance specification by both drug substance manufacturer of Dexlansoprazole (M/s. Enal Drugs Private Limited) and drug product (bulk) manufacturer of Dexlansoprazole pellets 22.5% (M/s. Alphamed Formulations Private Limited) as per requirement of innovator specification. One typical batch comparative results from both drug substance manufacturer and drug product manufacturer has been submitted. • The firm submitted that Dissolution specification set by the drug substance manufacturer are adopted from FDA website of Dissolution. • Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by drug product manufacturer for drug substance is attached.
3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis	Firm has submitted results of analysis of relevant batches of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from

	(CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. (batch number of both supplier and manufacturer are different)	drug substance/ Active Pharmaceutical Ingredient manufacturer
3.2.P.2	The applied product is 30mg capsule while the submitted CDP is for 60mg caps, clarify	The firm have submitted Comparative dissolution profile of Dexlansoprazole 30mg DR Capsules conducted against innovator product Dexilant capsule 30mg, in 0.1N HCl, Phosphate Buffer pH 5.5 and Phosphate buffer of pH 7.0 with SLS. The results of f2 factor are in acceptable range.
3.2.P.4	• Justify the use of gelatine capsule shell in dexlansoprazole capsule since innovator product has specified hypromellose capsule shells.	We have performed compatibility studies of Dexlansoprazole pellets 22.5% with hard gelatine capsule shells and found compatible for Dexlansoprazole pellets.
3.2.P.5	• Justify the dissolution specification set by the drug product manufacturer (0.1N HCl, Buffer pH 5.5 and Buffer pH 7) since they are different from the innovator dissolution specifications (0.1N HCl, pH 5.5 and pH 6.75). • The tests of loss on drying was not included in the submitted specifications as recommended by literature of innovator product.	• The firm submitted that Dissolution specification set by the drug product manufacturer are harmonized with the Dissolution Methods on FDA website which is "Acid stage: 0.1N Hydrochloric acid, Buffer stage: pH 7.0 Phosphate Buffer with 5mM Sodium Lauryl Sulphate". Besides, for dual delayed release effect determination, with reference to DRB 278th Meeting as advised to M/s. Weatherfolds Pharmaceuticals, Hattar, we have included pH 5.5 buffer stage dissolution. Furthermore, the specifications has also validated through comparative dissolution profile studies as per requirement of innovator's specification and found both products pharmaceutical equivalent. • The firm submitted that We are including the test of water content in the specifications as recommended by literature of innovator product. Proposed specifications are submitted
3.2P.8	• The results of batch analysis and stability data reflect that tests of content uniformity have not been performed throughout stability studies. Justify your stability study data without performance of this tests. • Submit readable copy of both the commercial invoice for evidence of purchase of pellets	• The stability specification has been established in-line with ICH Q 1A – 1F. Stability studies should include testing of those attributes of the drug product that are susceptible to change during storage and are likely to influence quality, safety, and/or efficacy. The testing should cover, as appropriate, the physical, chemical, biological, and microbiological attributes. Furthermore, Uniformity of dosage units (content uniformity) is an in-process control test and it is well controlled during release of drug product. Q1F Stability Guideline WHO 2018 is being submitted • The firm has submitted two copies of invoice No# GE2020/177 dated 30-11-202 and invoice No#GS2020/8 dated 17-06-2020 confirming the import of 6kg and 9kg dexlansoprazole dual delayed release pellets 22.5% w/w respectively attested by AD (I&E) DRAP Karachi.

Decision: Approved with innovators specifications.

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

• **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**		
376.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Ltd, B-18, S.I.T.E, Karachi.
	Name, address of Manufacturing site.	M/s Atco Laboratories Ltd, B-18, S.I.T.E, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25530 dated 14/09/2021
	Details of fee submitted	PKR 30,000/-: dated 15/06/2021 PKR 120,000/-: dated 26/07/2021 (balance fee) Total PKR 150,000/-: (Imported Pellets Fee)
	The proposed proprietary name / brand name	Dexlansoprazole DR Capsule 60mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole MS 60mg (as enteric coated pellets)
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	In house
	Proposed Pack size	7s, 10s, 14s, 20s, 28s & 30s.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Delanzo DR Capsule 60mg by M/s SAMI Pharmaceuticals (Reg# 089146)
	GMP status of the Finished product manufacturer	The firm was inspected on 28-02-2017 for renewal of DML and conclusion of inspection was: Keeping in view good facilities provided for manufacturing and quality control of pharmaceutical products registered in the name of firm being produced at site the overall good maintenance of plant and the required documentation and standards operating procedures were also found to be in place, the panel recommended the grant of renewal of Drug Manufacturing License No. 000188 (Formulation) of the firm.
	Name and address of API manufacturer.	**Source of Pellets:** Alphamed Formulations Pvt., Limited Survey No.225, Sampanbole Village, Shamirpet Mandal, Medchal Malkajgiri District Telangana - 500 101, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (AJ2A7004, AJ2A7005, AJ2A7006)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product that is Dexilant 60mg Capsule by Takeda Pharmaceuticals America, Inc by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Dexilant 60mg Capsule by Takeda Pharmaceuticals America, Inc in Acid media (pH 1.0-1.2), Phosphate Buffer (pH 5.5) & Phosphate Buffer (pH 7 with SLS). The values for f2 is in the acceptable range
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Source of Pellets: Alphamed Formulations Pvt., Limited., Survey No.225, Sampanbole Village, Shamirpet Mandal, Medchal Malkajgiri District Telangana - 500 101, India		
API Lot No.	AJ4A0003/B, RD-0050-023, RD-0050-024		
Description of Pack (Container closure system)	Alu-alu Blisters, packed in printed carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	AU228B	AU229B	AU230B
Batch Size	11200 caps	11200 caps	11200 caps
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	12-2020	12-2020	12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of Rofl 500mcg tablet on the

		basis of which Registration Board in its 277th meeting dated 27-29 December, 2017 decided to approve registration of Rofl 500mcg tablet. Inspection date: 10-10-2017 The report shows that: The HPLC software is 21 CFR compliant. Adequate monitoring and control are available for stability chambers
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP issued by Drug Control Administration, Government of Telangana India valid till 29/08/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted two copies of invoice confirming the import of 6kg and 9kg dexlansoprazole dual delayed release pellets respectively attested by AD (I&E) DRAP Karachi. Invoice # and date, supplier and receiver details are not clearly readable
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator XI:

Section	Observations	Response
	• Submit latest GMP inspection report conducted with in last three years	The firm has submitted cGMP certificate issued on 24-12-2020 base on inspection conducted on 06th November 2020
1.5.2	• Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit shall be clearly mentioned indicating the type and concentration of pellets	The have submitted label claim as under: Each capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5% w/w eq. to Dexlansoprazole: 60mg
3.2.S.4	• Justification is required for not including the test for Percentage of enantiomer in specification by drug substance manufacturer and drug product manufacturer although stated by the innovator product? (drug is racemic mixture) • Justify the dissolution specification set by the drug substance manufacturer (0.1N HCl, Buffer pH 6 and Buffer pH 7.4) since they are different from the innovator dissolution specifications (0.1N HCl, pH 5.5 and pH 6.75). • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Enantiomer is the process related impurity of pure API manufacturing of Dexlansoprazole and well controlled in drug substance specification by both drug substance manufacturer of Dexlansoprazole (M/s. Enal Drugs Private Limited) and drug product (bulk) manufacturer of Dexlansoprazole pellets 22.5% (M/s. Alphamed Formulations Private Limited) as per requirement of innovator specification. One typical batch comparative results from both drug substance manufacturer and drug product manufacturer has been submitted. • The firm submitted that Dissolution specification set by the drug substance manufacturer are adopted from FDA website of Dissolution. • Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by drug product manufacturer for drug substance is submitted.
3.2.S.4.4	• Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product	Firm has submitted results of analysis of relevant batches of Drug Substance performed by Drug Product manufacturer used during product

	manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	development and stability studies, along with Certificate of Analysis (CoA) of the same batch from drug substance/ Active Pharmaceutical Ingredient manufacturer
3.2.P.2	• As per WHO guideline surfactants should be avoided in comparative dissolution testing while you have used surfactant in CDP, clarify?	The firm submitted Surfactant should be avoided in comparative dissolution testing as the use of surfactants results in loss of discriminatory power of dissolution method. In this case, drug is not released in uniform pattern without surfactant due to solubility issue of Dexlansoprazole while release profile is the mandatory for comparative dissolution testing. Furthermore, the use of surfactant did not disturbed the release profile and the Active Pharmaceutical Ingredient releases gradually from the dual delayed release pellets and the discriminatory power of dissolution method is not loss as these pellets are dual delayed release, designed to release till large intestine in vivo. Results of Comparative dissolution profile of Dexlansoprazole pellets without surfactant in pH 7.0 buffer medium is submitted for reference.
3.2.P.4	• Justify the use of gelatine capsule shell in dexlansoprazole capsule since innovator product has specified hypromellose capsule shells.	We have performed compatibility studies of Dexlansoprazole pellets 22.5% with hard gelatine capsule shells and found compatible for Dexlansoprazole pellets.
3.2.P.5	• Justify the dissolution specification set by the drug product manufacturer (0.1N HCl, Buffer pH 5.5 and Buffer pH 7) since they are different from the innovator dissolution specifications (pH 5.5 and pH 6.75). • The tests of loss on drying was not included in the submitted specifications as recommended by literature of innovator product.	• The firm submitted that Dissolution specification set by the drug product manufacturer are harmonized with the Dissolution Methods on FDA website which is "Acid stage: 0.1N Hydrochloric acid, Buffer stage: pH 7.0 Phosphate Buffer with 5mM Sodium Lauryl Sulphate". Besides, for dual delayed release effect determination, with reference to DRB 278th Meeting as advised to M/s. Weatherfolds Pharmaceuticals, Hattar, we have included pH 5.5 buffer stage dissolution. Furthermore, the specifications has also validated through comparative dissolution profile studies as per requirement of innovator's specification and found both products pharmaceutical equivalent. • The firm submitted that We are including the test of water content in the specifications as recommended by literature of innovator product. Proposed specifications are submitted
3.2P.8	• The results of batch analysis and stability data reflect that tests of content uniformity have not been performed throughout stability studies. Justify your stability study data without performance of this test. • Submit readable copy of both the commercial invoice for evidence of purchase of pellets • The quantity of imported drug substance as per submitted invoice is 15kg and three batches of 30mg dexlansoprazole capsule each of 22500 caps and 60mg	• The stability specification has been established in-line with ICH Q 1A – 1F. Stability studies should include testing of those attributes of the drug product that are susceptible to change during storage and are likely to influence quality, safety, and/or efficacy. The testing should cover, as appropriate, the physical, chemical, biological, and microbiological attributes. Furthermore, Uniformity of dosage units (content uniformity) is an in-process control test and it is well controlled during release of drug product. Q1F Stability Guideline WHO 2018 is being submitted • The firm has submitted two copies of invoice No# GE2020/177 dated 30-11-202 and invoice

	dexlansoprazole capsule each of 11200 caps were manufactured from it. Justification is required as how the imported drug substance was sufficient enough to manufacture three batches of each strength.	No#GS2020/8 dated 17-06-2020 confirming the import of 6kg and 9kg dexlansoprazole dual delayed release pellets 22.5% w/w respectively attested by AD (I&E) DRAP Karachi. • The firm submitted that initially, during development stage, we have also received 6Kg pellets received from two lots of pellets (3Kg from each lot) for development and trial purpose as FOC. The total quantity received is 21Kg while approx. 18Kg pellets has been consumed in preparation of three batches of 30mg Dexlansoprazole capsules each of 22500 caps and three batches of 60mg Dexlansoprazole capsules each of 11200 caps

Decision: Approved with innovators specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 02: Registration applications of New Section of human drugs

a. M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha (New Sections).

The Central Licensing Board in its 276th meeting held on 3rd September, 2020 has considered and approved the following additional section of M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha. under Drug Manufacturing License No. 000609 (Formulation) vide approval letter No. F. 1-37/2003-Lic (Vol-I) dated 29th September 2020.

S No.	Section
1.	Capsule (General) Section (New)
2.	Sachet (General) Section (New)

Following applications have been submitted for registration by the firm.

377.	Name, address of Applicant / Marketing Authorization Holder	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3134 dated 01-02-2022
	Details of fee submitted	PKR 30,000/-: dated 16-12-2021
	The proposed proprietary name / brand name	Diclomax SR 100 mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains:

		Diclofenac Sodium SR Pellets 32% eq. to Diclofenac Sodium……..100 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	NSAID (Non-steroidal anti-inflammatory drugs)
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rhumalgan XL 100mg modified-release capsules, MHRA Approved.
	For generic drugs (me-too status)	Phlogin-100 capsule by M/s Brookes Pharmaceuticals (Reg#009129)
	GMP status of the Finished product manufacturer	New sections
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals, Plot No.22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 36 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. Batches: (DE062ER, DE230ER, DE160ER)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Phlogen SR 100mg Capsule by M/s Brooks Pharmaceuticals by performing quality tests (Identification,-Assay, Dissolution). CDP has been performed against the same brand Phlogen SR 100mg Capsule by M/s Brooks Pharmaceuticals in Acid media 0.1N HCl (pH 1.2),

		acetate buffer (pH 4.5) & phosphate Buffer (pH 6.8). The values are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals, Plot No.22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	DE812ER		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T1/21	T2/21	T3/21
Batch Size	2000 Cap	2000 Cap	2000 Cap
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	25-01-2021	25-01-2021	25-01-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm submitted that Quaper Pvt. Ltd is a new license facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm submitted copy of GMP certificate No.F.3-26/2019-Addl. Dir. (QA &LT-I) dated 31st July 2019 of M/s Vision Pharmaceuticals valid up to 10/02/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for 2kg of Diclofenac Sodium SR pellets 32% from Vision Pharmaceuticals (Pvt.) Ltd
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm have submitted data of stability batches along with respective documents like Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not required as Assay and dissolution performed on UV
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm have submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
	• Submit valid GMP certificate of drug substance manufacturer i.e. Vision Pharma	Firm has submitted copy of application and fee deposit slip submitted to DRAP for issuance of new GMP certificate to Vision Pharma
1.5.15-1.5.20	• Commitments not submitted as per the CTD guidance document	Firm has submitted commitments as per the CTD guidance document
3.2.S.4.	• Copies of the analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical	Firm has submitted copies of the analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.

	Ingredient by Drug substance manufacturer is required.	
3.2.P.2.2.1	• Justification is required since pharmaceutical equivalence and CDP studies have not been conducted against the innovator product.	Due to non-availability of innovator product in the market, available brand of well reputed company was used for pharmaceutical equivalence and CDP studies.
3.2.P.4.5	• For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE. • Halal certificate for gelatin shall be provided	The firm have submitted statement regarding TSE/BSE/GMO from M/s Multicaps capsule for quality product Karachi. It is certified that we manufacturer Empty Hard capsules from halal gelatin. It is derived form the bovine bones of halal animals. We hereby declare that our product is free from Transmissible Spongiform Encephalopathy (TSE), Bovine Spongiform Encephalophathy and also free from Genetically Modified Organism (GMO).
3.2.P.5	• Justification shall be submitted for applying UV spectrum for identification of the diclofenac sustained released capsule while BP specifies identification of diclofenac sodium prolonged release capsule by IR method. • Justification shall be submitted for selecting Q NLT 70% in buffer pH 7.2 after 8 hr?	• Copy of IR spectrum for identification of diclofenac sodium as per BP specification is submitted • ***Limit for Q NLT 70% in buffer pH 7.2 after 8 hr is selected as per drug substance manufacturer specifications***
3.2.P.8	• You have mentioned the batch size 1600caps in batch T1/21 in stability summary sheet while 2000caps in two other batches, clarify as the batch size should be same for all batches manufactured?	The firm submitted that there was a typographical error. In actual the batch size for all three stability batches was 2000 capsule. The firm have submitted corrected summary sheet

Decision: Approved.

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

b. M/s Invictus Pharmaceuticals Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat".

The Central Licensing Board in its 273rd meeting held on 15th January, 2020 has considered and approved the following three (03) sections of "M/s Invictus Pharmaceuticals Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat" under Drug Manufacturing License No. 000892 (Formulation) vide approval letter No. F. 1-37/2016-Lic (Vol-I) dated 18th February 2020.

S No.	Section
1.	Dry Powder Injection Section (Cephalosporine)
2.	Dry Powder for suspension Section (Cephalosporine))
3.	Capsule Section (Cephalosporine)

Following applications have been submitted for registration by the firm.

378.	Name, address of Applicant / Marketing Authorization Holder	Invictus Pharmaceuticals., NS2, Rawalpindi, Rawat Industrial Estate, Islamabad, Rawalpindi, Islamabad Capital Territory
	Name, address of Manufacturing site.	Invictus Pharmaceuticals., NS2, Rawalpindi, Rawat Industrial Estate, Islamabad, Rawalpindi, Islamabad Capital Territory
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23341 dated 26-08-2021
	Details of fee submitted	PKR 30,000/-: dated 26-07-2021
	The proposed proprietary name / brand name	Cef-Vic 400mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Cefixime as Trihydrate…….400mg
	Pharmaceutical form of applied drug	White to off white powder filled in Size "0" Shell and packed in Alu-Alu pack of 5's.
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	Alu/Alu of Pack size of 5's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg Capsule by M/s Alkem Labs Ltd USFDA approved
	For generic drugs (me-too status)	Cebosh 400mg Capsule by M/s Bosch Pharmaceuticals (Reg# 027160)
	GMP status of the Finished product manufacturer	New section
	Name and address of API manufacturer.	Pharmagen Limited., Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Tel: +92 (042) 5935261-68 Fax: +92 (042) 5935269 E-mail: pblbd@hotmail.com Web: www.pharmagen.com.pk
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{O} \pm 2^{O}$ C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2^{O} C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence and comparative dissolution profile against the product Cefspan Capsule 400mg by M/s Barrett Hodgson (Pvt) Ltd
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA

Manufacturer of API manufacturer	Pharmagen Limited., Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Tel: +92 (042) 5935261-68 Fax: +92 (042) 5935269 E-mail: pblbd@hotmail.com Web: www.pharmagen.com.pk		
API Lot No.	00243/078/2020		
Description of Pack (Container closure system)	The granular dry powder for capsule will be filled in a Size "0" Empty Hard Gelatin Shell and blistered in Alu/Alu of Pack size of 5's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	Tc-001	Tc-002	Tc-003
Batch Size	2500	2500	2500
Manufacturing Date	05-20	05-20	05-20
Date of Initiation	13-05-20	13-05-20	13-05-20
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of M/s Pharmagen Limited issued on 11.01.2019 based on inspection conducted on 08.01.2019

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Applicable
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC [XI]:

Section	Observations	Response
1.3.3	Specify the status of applicant as you have submitted that applicant "Is involved in none of the above (contract giver)" in module 1 of form 5F	The firm have submitted revised form 5-F and specified the status of applicant as "manufacturer"
1.3.1.-1.3.2	The address mentioned in submitted application is different from the address mentioned on DML, clarify?	The firm have submitted revised form 5-F and corrected the address as per DML
1.5.6	In Form 5F you have mentioned innovator's specifications for the product under section 1.5.6. while the monograph of applied product is available in JP, clarify?	***The firm have revised the specifications to JP specifications***
2.3.	Submit module 2 as per WHO QOS-PD template without referring to any annexure of Module III.	Firm have submitted module 2 as per WHO QOS-PD template
3.2.S.4.1.	As per the drug substance specifications of the drug substance manufacturer i.e. M/s Pharmagen Limited, the firm submitted that material complies BP, USP and in-house specifications, justification is required as how the drug substance follow all the specifications	The firm have submitted certificate of analysis of drug substance in which the drug substance follows USP specifications
3.2.S.4.1. -3.2.S.4.2	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Drug substance specification and analytical procedure of Invictus Pharmaceuticals is provided. ***However, the analytical procedure does not contain procedure for identification test (IR), pH, water content and specific rotation as recommended by USP and contain only procedure for assay test.***
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	***No reply submitted***
3.2.S.4.4	The Batch No. mentioned in batch analysis by drug substance manufacturer is 00243/078/2020 while the Batch No. mentioned in batch analysis by drug product manufacturer 00243/264/2020, clarify?	The firm submitted that batch No. of the drug substance cefixime used is 00243/078/2020 and submitted COA of drug substance from drug substance manufacturer and drug product manufacturer. The firm further stated that compacted cefixime is used in formulation of

<table>
<tr><td></td><td>Furthermore, COA submitted by the drug substance manufacturer and drug product manufacturer shows that micronized cefixime was used in formulation of cefixime capsule, clarify?</td><td>cefixime capsule as depicted in COA. However, COA of same batch number of API was submitted for micronized form of cefixime previously.</td></tr>
<tr><td>3.2.P.1</td><td>• The composition of applied product is not as per innovator’s product, clarify
<table>
<tr><td>Applied product</td><td>SUPRAX 400mg capsules</td></tr>
<tr><td>Cefixime trihydrate</td><td>Cefixime trihydrate</td></tr>
<tr><td>Colloidal silicon dioxide</td><td>Colloidal silicon dioxide</td></tr>
<tr><td></td><td>Crospovidone</td></tr>
<tr><td>Microcrystalline cellulose 102</td><td>Low Substituted Hydroxy Propyl Cellulose,</td></tr>
<tr><td>Magnesium Stearate,</td><td>Magnesium Stearate,</td></tr>
<tr><td>EHG Capsule shell ‘0’ size</td><td>Mannitol</td></tr>
<tr><td></td><td></td></tr>
</table>
• Quantity of cefixime per unit dose shall be justified with equivalency factor for cefixime trihydrate.
• You have mentioned the use of overages in your formulation to compensate the potency of the product during process loss, justify?</td><td>• The response is submitted in subsection 3.2.P.2.1.1
• Quantity of cefixime per unit dose and per batch have been explained and justified based upon the salt factor calculation and assay results. The justification is submitted.
• Firm has used the theoretical factor for adjustment of water content while dispensing, instead of the actual results of “water content test” reported in the drug substance analysis.
• The firm submitted that we have used no overages in our formulation</td></tr>
<tr><td>3.2.P.2.2.1</td><td>• Firm has performed pharmaceutical equivalence against the product Cefspan Capsule 400mg by M/s Barrett Hodgson (Pvt) Ltd. Justification is required as comparator product fails the dissolution test, then how product is pharmaceutical equivalent. (Limit NLT 80%, test result 69.82%.)
• Time point for CDP conducted is 30, 45, 60min. 15 min time point is not considered being necessary as per WHO guidelines.</td><td>• Firm has again submitted pharmaceutical equivalence of applied product against the product Cefspan Capsule 400mg by M/s Barrett Hodgson (Pvt) Ltd and the results of tests are within range.
• No reply submitted</td></tr>
<tr><td>3.2.P.2.1.1</td><td>Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.</td><td>The firm have submitted that applied formulation contains colloidal silicon dioxide, magnesium stearate and microcrystalline cellulose as per reference formulation. The stability studies of the product show that all the test, physical appearance dissolution and assay are within limits and there are no changes developed during stability.</td></tr>
<tr><td>3.2.P.5.2</td><td>• Provide signed copy of analytical methods used for applied product
• Justification for proposed analytical procedure is required as the official monograph is available in JP</td><td>• The firm submitted that product complies JP specifications and analytical method and JP monograph is submitted. However, JP monograph for applied product was not</td></tr>
</table>

	• The firm have proposed UV spectrophotometric method for assay of drug product while the JP monograph recommends HPLC for assay analysis	***submitted and analytical was submitted only for assay test and dissolution test.*** • The firm submitted that there was a typographical mistake we have use the submitted method and HPLC chromatograms are attached. ***However, no chromatograms were submitted***
3.2.P.5.4	• In finished product specifications under section 3.2.P.5.1 you have applied in house specifications while in Batch Analyses you confirmed that product complies with USP specifications, clarify?	The firm submitted that product complies JP specifications and stated that JP monograph is attached. ***However, no JP monograph was submitted***
3.2.P.6	• The working standard used during analysis states that it should be used before July 2020 while 3rd month stability study performed in august 2020 and 6th month stability study performed at November 2020 using the same working standard • The firm have provided COA of primary reference standard for drug substance analysis and COA of working standard. However, the standardization of working standard is performed with other Reference Standards, the COA of which is not provided	• The firm have submitted valid COA of working standard. • The firm have submitted COA of primary reference standard and standardization of working standard has been performed against the same primary reference standard.
3.2.P.8	• Submit Raw data sheets, COA & analytical record for both assay & dissolution test containing detail of sample preparation, standard preparation for various performance parameters. • The date of initiation mentioned in stability study is 13.05.2020 while the date of manufacturing mentioned in BMR is 18.05.2021. Clarify how stability study started before the manufacturing of batch.	• Firm have submitted Raw data sheets, including actual details of sample solution preparation & standard preparation, weight of standard & calculation formula applied for assay test only. ***Raw data sheets and COA for dissolution test containing detail of sample preparation, standard preparation for various performance parameters is not submitted.*** • The firm submitted that there was a typographic mistake. The initiation date is 18-05-2021 as mentioned in BMR

Decision: Deferred for following:

- **Submission of analytical procedures & analytical record for testing of the Drug substance by Drug Product manufacturer as per USP monograph.**
- **Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) for drug substance performed by the Drug Product manufacturer**
- **Justification how same batch of drug substance (Batch No. 00243/078/2020) is used both as compacted and micronized.**
- **Submission of CDP as per WHO guidelines against innovator product**
- **Revision of specification as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.**
- **Performance of batch analysis as per the monograph approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.**

c. M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore

The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has considered and approved the grant of following sections of **M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore** under Drug Manufacturing License No. 000779 (Formulation) vide approval letter No. F. 1-11/2009-Lic (Vol-I) dated 10th May, 2022.

S No.	Section

1.	Tablet Section II (General) **New**
2.	Dry Powder Suspension Section. **New**
3.	Dry Powder Sachet Section (General). **New**

Following applications have been submitted for registration by the firm.

379.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17860 dated 20/06/2022
	Details of fee submitted	PKR 30,000/-: dated 10/06/2022 (slip No#392967182013)
	The proposed proprietary name / brand name	Azipos 200mg /5ml Dry Powder Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Azithromycin as dihydrate……..200mg
	Pharmaceutical form of applied drug	Dry Powder suspension (Azithromycin dihydrate 35% Taste masked micropellets)
	Pharmacotherapeutic Group of (API)	Macrolides
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	15ml, 25ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zithromax for oral suspension 200mg/5ml USFDA Approved
	For generic drugs (me-too status)	Azomax 200mg Oral Suspension by M/s Sandoz (Pakistan) Ltd (Reg#022201)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AZI 112, AZI 111, AZI 115)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed Pharmaceutical Equivalence of their product Azipos 200mg dry powder suspension against the Azomax dry powder suspension 200mg/5ml by M/s Novartis Pharma and found that both products are equivalent to each other.
	Analytical method validation/verification of product	Firm has submitted method verification report for the applied product

STABILITY STUDY DATA			
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591		
API Lot No.	AZI 154		
Description of Pack (Container closure system)	Amber colored glass bottle with Aluminium P.P caps printed with company logo		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AZ-02	AZ-03	AZ-04
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	27-11-2021	27-11-2021	27-11-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of their product on the basis of which Registration Board in its 289th meeting held on 14-16th May, 2019 decided to approve registration of Delanso 30mg capsule and Delanso 60mg capsule. Inspection date: 02nd May, 2019 The report shows that:

		• The firm have quaternary gradient HPLC (Shimadzu; Model; LC20AT); with time and date locked but it is not 21 CFR compliant. • Power backup by UPS and 200kv generator was available. Digital data logger was not installed for continuous monitoring and control of stability chambers. Storage conditions were being recorded thrice daily manually.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of all three batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
	Firm has stated that they have R&D section as date of manufacturing of batches is November 2021 and grant of additional section is March 2022	
1.4.1	You have stated that the submitted application is for registration of New Drug Product while the applied product is Generic drug product, clarify?	The firm submitted that we have applied for generic drug product but typographic error it was highlighted as new drug molecule
1.6.5	Submit valid GMP certificate of drug substance manufacturer	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022. The firm further submitted that vision pharma has already submitted request for cGMP inspection on 22-12-2021 along with requisite fee.
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Firm has submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance

3.2.P.5	• Time for dissolution test is not specified in submitted specifications of applied product • The limits of pH test (8.5-11) in submitted specification is different from that recommended by USP (9-11) • The calculation formula used for assay calculation is different from that recommended by USP clarify? • The injection volume mentioned in chromatographic conditions of assay (applied 20ul and USP 50ul) and dissolution test (applied 20ul and USP 100ul) in submitted analytical procedure is different from that recommended by USP. • The calculation formula used for dissolution is different from that recommended by USP clarify?	• The firm have revised specification and mentioned time for dissolution test in specifications. • The firm submitted that acceptance criteria of pH for multiple unit containers is 8.5-11 as per USP. • The firm submitted that We used convention equation for the calculation of Assay now we have updated our testing method as per USP. It's notable that the results are same by applying both calculations. • The firm submitted that Sample and standard were analyzed under same chromatographic conditions (including the same injection volume) and found that the results were closely comparable. • USP <621> states that injection volume can be adjusted as it is consistent with acceptable precision (evidence submitted herewith). • It is remarkable that we have performed analytical method validation in which we did extensive testing taking different concentrations under heading of Limit of Detection, Limit of Quantification, Linearity, Accuracy and Recovery. Results of above said validation parameters complied with the Relative Standard Deviation limits. • The firm submitted that We used convention equation for the calculation of Dissolution now we have updated our testing method as per USP. It's notable that the result are same by applying both calculations
3.2.P.8	• Tests for antimicrobial preservative content and efficacy of preservative as recommended by ICH Q1 (R2) guidelines and USP chapter <51> should be performed for finished product • In use stability study of reconstitution suspension shall be submitted • Submit documents for the procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	• The firm have submitted Tests for antimicrobial preservative content and efficacy of preservative for only one batch. • Firm have submitted protocol for in use stability study of reconstitution suspension. However, firm have not submitted result of in use stability study of reconstitution suspension • The firm has submitted copy of invoice No# 60008 dated 29-10-2021 from vision pharmaceutical confirming the purchase of 550gm azithromycin Diydrate T.M Micropellets 35% batch No#AZI154 in name of Titlis Pharma • We have performed the stability study of Azipos 200mg/5ml Dry powder suspension on our HPLC (QC-HPLC-001) SHIMAZDZU Model No. LC-20 AT, which is not 21CFR Compliant. • However, it is certified that **date and time of this HPLC (QC-HPLC-001) is locked and data alteration/editing is strictly restricted**. Moreover this HPLC

		(QC-HPLC-001) has access control and only two authorized QC analysts have authorization to access and operate this HPLC (QC-HPLC-001). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is submitted

Decision: Approved.

- **Registration letter will be issued after submission of Tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> for finished product as well as In use stability study of reconstitution suspension**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

380.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11089 dated 07/05/2022
	Details of fee submitted	PKR 30,000/-: dated 10/02/2022 (slip No#56031211)
	The proposed proprietary name / brand name	Dapatit 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Dapagliflozin as propanediol monohydrate …….5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA (5mg, 10mg) film coated tablets USFDA Approved

	For generic drugs (me-too status)	Dapa 5mg Tablet by M/s Hilton Pharma (Reg#089367)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	M/s Fuxin Long Rui Pharmaceuticals CO., Ltd, Fluoride Industrial Park, Fumeng county (Yi Ma Tu), Fuxin city, Liaoning Province- 123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Dapa 5mg Tablet of M/s Hilton Pharma by performing quality tests (disintegration, weight variation, Assay, Dissolution, of dosage form). CDP has been performed against the same brand that is Dapa 5mg Tablet of M/s Hilton Pharma in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceuticals CO., Ltd, Fluoride Industrial Park, Fumeng county(Yi Ma Tu), Fuxin city, Liaoning Province- 123000, China		
API Lot No.	L-DG-20210418-D01-DG06-01		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DP-01	DP-02	DP-03

<table>
<tr><td colspan="2">Batch Size</td><td>1,000 tablets</td><td>1,000 tablets</td><td>1,000 tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>Sep-2021</td><td>Sep-2021</td><td>Sep-2021</td></tr>
<tr><td colspan="2">Date of Initiation</td><td>29-10-2021</td><td>29-10-2021</td><td>29-10-2021</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="5">Administrative Portion</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">The firm has referred to previous inspection for authenticity of stability data of their product on the basis of which Registration Board in its 289th meeting held on 14-16th May, 2019 decided to approve registration of Delanso 30mg capsule and Delanso 60mg capsule.
Inspection date: 02nd May, 2019
The report shows that:
• The firm have quaternary gradient HPLC (Shimadzu; Model; LC20AT); with time and date locked but it is not 21 CFR compliant.
• Power backup by UPS and 200kv generator was available. Digital data logger was not installed for continuous monitoring and control of stability chambers. Storage conditions were being recorded thrice daily manually.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceuticals CO., Ltd, Fluoride Industrial Park, Fumeng county (Yi Ma Tu), Fuxin city, Liaoning Province- 123000, China for Active substance Dapagliflozin Propanediol Monohydrate issued by Liaoning Drug Administration P.R China confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">The firm has submitted copy of commercial invoice attested by AD I&E DRAP, Lahore dated 12-08-2021
<table>
<tr><th>Invoice No. & date</th><th>Batch No.</th><th>Quantity Imported</th></tr>
<tr><td>HN210630-J dated 30-06-2021</td><td>L-DG-20210418-D01-DG06-01
L-DG-20210418-D01-DG06-02
L-DG-20210418-D01-DG06-03</td><td>0.150 kg
0.005 kg
0.005 kg</td></tr>
</table>
The invoice is issued from M/s Beijing Sino Hason Import & Export Co., Ltd in the name of M/s Titlis Pharma (Pvt) Ltd and it does not contain the name of manufacturer.</td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted stability study data of all three batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td colspan="3">Not submitted</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td colspan="3">Not submitted</td></tr>
<tr><td colspan="5">Remarks of Evaluator [XI]:</td></tr>
</table>

Section	Observations	Response
	Firm has stated that they have R&D section as date of manufacturing of batches is September 2021 and grant of additional section is March 2022	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Firm has submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance
3.2.P.2	• You have not performed CDP and pharmaceutical equivalence against the innovator brand justify? • Justification is required as your formulation contains Ac-Di-Sol (croscarmellose) while innovator product does not contain this excipient?	• The firm submitted that innovator product is not registered in Pakistan therefore, Comparative dissolution profile of Dapatit 5mg Tablet was performed against the reference product Dapa 5mg Tablet manufactured by Hilton Pharma (Pvt) Limited which is available in the market. • The firm further stated that the data of comparative dissolution profile report for Dapatit 5mg tablet is remarkable and the product is highly soluble and dissolves more than 80% within 15minutes in all three media (0.1 N HCl pH 1.2, Acetate buffer pH 4.5 and Phosphate buffer pH 6.8) at all sampling points. The results show that dissolution profile of test and reference products are almost similar. • Moreover, f2 values comply with the acceptance criteria. • The firm submitted that Formulation of Dapatit 5mg Tablet is as similar as the formulation of innovator product except AC-Di-Sol (croscarmellose) in its composition. • The firm submitted that AC-Di-Sol is an inert excipient, has compatibility with other excipients and active pharmaceutical ingredient of Dapatit 5mg tablet. Its safety and compatibility have also been established as no harsh / adverse effect has been observed in our stability studies. • As per literature review and study of Hand Book for Pharmaceutical Excipients, it is notable that the said excipient enhances disintegration, dissolution and performance of the tablet which is very clearly depicted from the comparative dissolution profile studies of Dapatit 5mg Tablet.
3.2.P.5	• Justify the dissolution studies at 75 rpm, 0.1N HCl (900ml) and 45 min since the innovator product review documents specifies 60 rpm, acetate buffer pH 4.5 (1000ml) and 15 min for dissolution studies.	• The firm submitted that Initially we performed dissolution by using following parameters: Media: 0.1N HCl (900ml), RPM: 75, Apparatus: II (Paddle), Time 45 min. • Stability batches were analyzed at 0, 3, & 6 months on in house testing but after reviewing the FDA drug approval /literature review **(FDA reviewing document**, we revised our testing method as follows: **Media: Acetate buffer (pH 4.5) 1000ml** **RPM: 60** **Apparatus: II (Paddle)** **Time 15 min.**

		We develop the following protocol for stability studies **1. To manufacture 3 new batches (Batch numbers: DP-07, DP-08 and DP-09) for performance of accelerated and long run stability testing as per innovator's specifications / dissolution parameters.** • We have analyzed these batches as per innovator's specifications / dissolution parameters; and "0", 3rd month testing has been completed and results are complying with innovator specification which are submitted **2. To perform one-month stress testing at 60℃ ± 2℃ / 75% ± 5% RH on samples of ongoing stability studies as per innovator's specifications / dissolution parameters.** • We have drawn samples from our ongoing stability studies and kept them on stress conditions for one month (from 12th July -2022 to 12th August-2022); and analyzed that results are complying with innovator specification. The Reports and chromatogram are being submitted **3. To perform the ongoing/long run stability studies of 9th month and other time intervals as per innovator's specifications / dissolution parameters.** • We have performed 9th month stability studies as per innovator's specifications / dissolution parameters and analyzed that results are complying with innovator specification. Reports and chromatogram are submitted • Moreover, we have performed 9th month stability study as per Titlis specifications and conclude that results are comparable. Results on both conditions are found similar and no impact observed in the results due to change in dissolution parameters. (Reports and chromatogram are submitted
3.2.P.8	• Submit documents for the procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	• The firm has submitted copy of form 6 No#12099/2021-DRAP dated 12-08-2021 from Fuxin Long Rui Pharmaceutical Co., Ltd., for the import of 0.16kg of Dapagliflozin propanediol Monohydrate attested by AD (I&E) DRAP Lahore. • We have performed the stability study of Dapatit 5mg Tablet on our HPLC (QC-HPLC-001) SHIMAZDZU Model No. LC-20 AT, which is not 21CFR Compliant. • However, it is certified that **date and time of this HPLC (QC-HPLC-001) is locked and data alteration/editing is strictly restricted**. Moreover, this HPLC (QC-HPLC-001) has access control and only two authorized QC

		analysts have authorization to access and operate this HPLC (QC-HPLC-001). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is submitted

Decision: Approved with innovators specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

381.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11088 dated 07/05/2022
	Details of fee submitted	PKR 30,000/-: dated 10/02/2022 (slip No#7997424171)
	The proposed proprietary name / brand name	Dapatit 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Dapagliflozin as propanediol monohydrate ….10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA (5mg, 10mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Dapa 10mg Tablet by M/s Hilton Pharma (Reg#089368)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022

	Name and address of API manufacturer.	M/s Fuxin Long Rui Pharmaceuticals CO., Ltd, Fluoride Industrial Park, Fumeng county (Yi Ma Tu), Fuxin city, Liaoning Province- 123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Dapa 10mg Tablet of M/s Hilton Pharma by performing quality tests (disintegration, weight variation, Assay, Dissolution, of dosage form). CDP has been performed against the same brand that is Dapa 10mg Tablet of M/s Hilton Pharma in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceuticals CO., Ltd, Fluoride Industrial Park, Fumeng county(Yi Ma Tu), Fuxin city, Liaoning Province- 123000, China		
API Lot No.	L-DG-20210418-D01-DG06-01		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DP-04	DP-05	DP-06
Batch Size	1,000 tablets	1,000 tablets	1,000 tablets
Manufacturing Date	Sep-2021	Sep-2021	Sep-2021
Date of Initiation	29-10-2021	29-10-2021	29-10-2021
No. of Batches	03		

<table>
<tr><td colspan="3">Administrative Portion</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td>The firm has referred to previous inspection for authenticity of stability data of their product on the basis of which Registration Board in its 289th meeting held on 14-16th May, 2019 decided to approve registration of Delanso 30mg capsule and Delanso 60mg capsule.
Inspection date: 02nd May, 2019
The report shows that:
• The firm have quaternary gradient HPLC (Shimadzu; Model; LC20AT); with time and date locked but it is not 21 CFR compliant.
• Power backup by UPS and 200kv generator was available. Digital data logger was not installed for continuous monitoring and control of stability chambers. Storage conditions were being recorded thrice daily manually.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceuticals CO., Ltd, Fluoride Industrial Park, Fumeng county (Yi Ma Tu), Fuxin city, Liaoning Province- 123000, China for Active substance Dapagliflozin Propanediol Monohydrate issued by Liaoning Drug Administration P.R China confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of commercial invoice attested by AD I&E DRAP, Lahore dated 12-08-2021
<table>
<tr><th>Invoice No. & date</th><th>Batch No.</th><th>Quantity Imported</th></tr>
<tr><td>HN210630-J dated 30-06-2021</td><td>L-DG-20210418-D01-DG06-01
L-DG-20210418-D01-DG06-02
L-DG-20210418-D01-DG06-03</td><td>0.150 kg
0.005 kg
0.005 kg</td></tr>
</table>
The invoice is issued from M/s Beijing Sino Hason Import & Export Co., Ltd in the name of M/s Titlis Pharma (Pvt) Ltd and it does not contain the name of manufacturer.</td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted stability study data of all three batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Not submitted</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Not submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator [XI]:
<table>
<tr><th>Section</th><th>Observations</th><th>Response</th></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>3.2.S.4</td><td>• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product</td><td>Firm has submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision)</td></tr>
</table></td></tr>
</table>

	manufacturer for drug substance(s) shall be submitted.	performed by the Drug Product manufacturer for drug substance
3.2.P.2	• You have not performed CDP and pharmaceutical equivalence against the innovator brand justify? • Justification is required as your formulation contains Ac-Di-Sol (croscarmellose) while innovator product does not contain this excipient?	• The firm submitted that innovator product is not registered in Pakistan therefore, Comparative dissolution profile of Dapatit 10mg Tablet was performed against the reference product Dapa 10mg Tablet manufactured by Hilton Pharma (Pvt) Limited which is available in the market. • The firm further stated that the data of comparative dissolution profile report for Dapatit 10mg tablet is remarkable and the product is highly soluble and dissolves more than 80% within 15minutes in all three media (0.1 N HCl pH 1.2, Acetate buffer pH 4.5 and Phosphate buffer pH 6.8) at all sampling points. The results show that dissolution profile of test and reference products are almost similar. • Moreover, f2 values comply with the acceptance criteria. • The firm submitted that Formulation of Dapatit 10mg Tablet is as similar as the formulation of innovator product except AC-Di-Sol (croscarmellose) in its composition. • The firm submitted that AC-Di-Sol is an inert excipient, has compatibility with other excipients and active pharmaceutical ingredient of Dapatit 10mg tablet. Its safety and compatibility have also been established as no harsh / adverse effect has been observed in our stability studies. • As per literature review and study of Hand Book for Pharmaceutical Excipients, it is notable that the said excipient enhances disintegration, dissolution and performance of the tablet which is very clearly depicted from the comparative dissolution profile studies of Dapatit 10mg Tablet.
3.2.P.5	• Justify the dissolution limits NLT 75% in 45 minutes in specifications since innovator product review documents specifies 15 min for dissolution studies. • Justify the dissolution studies at 75 rpm, 0.1N HCl (900ml) and 45 min since the innovator product review documents specifies 60 rpm, acetate buffer pH 4.5 (1000ml) and 15 min for dissolution studies.	• The firm have revised dissolution specifications as Q….NLT 75% in 15 minutes. • The firm submitted that Initially we performed dissolution by using following parameters: Media: 0.1N HCl (900ml), RPM: 75, Apparatus: II (Paddle), Time 45 min. • Stability batches were analyzed at 0, 3, & 6 months on in house testing but after reviewing the FDA drug approval /literature review **(FDA reviewing document**, we revised our testing method as follows: **Media: Acetate buffer (pH 4.5) 1000ml** **RPM: 60** **Apparatus: II (Paddle)** **Time 15 min.** We develop the following protocol for stability studies **1. To manufacture 3 new batches (Batch numbers: DP-010, DP-11 and DP-12) for performance of accelerated and long run**

		stability testing as per innovator's specifications / dissolution parameters. • We have analyzed these batches as per innovator's specifications / dissolution parameters; and "0", 3rd month testing has been completed and results are complying with innovator specification which are submitted **2. To perform one-month stress testing at 60℃ ± 2℃ / 75% ± 5% RH on samples of ongoing stability studies as per innovator's specifications / dissolution parameters.** • We have drawn samples from our ongoing stability studies and kept them on stress conditions for one month (from 13th July -2022 to 13th August-2022); and analyzed that results are complying with innovator specification. The Reports and chromatogram are being submitted **3. To perform the ongoing/long run stability studies of 9th month and other time intervals as per innovator's specifications / dissolution parameters.** • We have performed 9th month stability studies as per innovator's specifications / dissolution parameters and analyzed that results are complying with innovator specification. Reports and chromatogram are submitted • Moreover, we have performed 9th month stability study as per Titlis specifications and conclude that results are comparable. Results on both conditions are found similar and no impact observed in the results due to change in dissolution parameters. (Reports and chromatogram are submitted
3.2.P.8	• Justify the manufacturing of trial batches for stability study in September 2021 as approval of new section is granted on 17th & 18th March, 2022 and new section letter issuance date is 10-05-2022. • Submit documents for the procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	• Firm has stated that they have R&D section and development of trial batches of Dapatit 10mg was performed in our development (R&D) section. • The firm has submitted copy of form 6 No#12099/2021-DRAP dated 12-08-2021 from Fuxin Long Rui Pharmaceutical Co., Ltd., for the import of 0.16kg of Dapagliflozin propanediol Monohydrate attested by AD (I&E) DRAP Lahore. • The firm submitted that We have performed the stability study of Dapatit 10mg Tablet on our HPLC (QC-HPLC-001) SHIMAZDZU Model No. LC-20 AT, which is not 21CFR Compliant. • However, it is certified that **date and time of this HPLC (QC-HPLC-001) is locked and data alteration/editing is strictly restricted**. Moreover, this HPLC (QC-HPLC-001) has access control and only two

		authorized QC analysts have authorization to access and operate this HPLC (QC-HPLC-001). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is submitted

Decision: Approved with innovators specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 3: Registration applications of New DML of human drugs on Form 5F

M/s Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat.
The Central Licensing Board in its 278th meeting held on 10th-11th December, 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five sections to M/s, Carer Pharmaceuticals Industries Plot # 27, Main Road, Rawat Industrial Estate, Rawat under Drug Manufacturing License No. 000925 by way of Formulation vide approval letter No. F. 1-32/2016-Lic dated 07th June 2021. **The Drug Manufacturing License No. 000925 by way of formulation is hereby issued w.e.f. 18-03-2021.**

S No.	Section
1.	Capsule Section (General) Section
2.	Dry Powder Suspension (General) Section
3.	Sachet (General) Section
4.	Ampoule (General) Section
5.	Tablet (General) Section

Following applications have been submitted for registration by the firm.

382.	Name, address of Applicant / Marketing Authorization Holder	M/s, Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s, Carer Pharmaceuticals Industries. Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29204 dated 26/10/2021
	Details of fee submitted	PKR 30,000/-: dated 18/10/2021
	The proposed proprietary name / brand name	Capliva 200mg /5ml Dry Powder Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Azithromycin as dihydrate……..200mg

	Pharmaceutical form of applied drug	Dry Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Macrolides
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's (15ml, 30ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zithromax powder for oral suspension 200mg/5ml by M/s Pfizer Ltd MHRA Approved
	For generic drugs (me-too status)	Zetro oral suspension 200mg by M/s Getz Pharma (Reg#047145)
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceutical Co, Ltd., No 9 Xingye street, Shiiazhuang Economic and Technological Development Zone, Hebei Province, China. Tel: 0086-575-82736468 Fax: 0086-575-82735575
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (U129-141124-1, U129-141125-1, U129-141126-1)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed Pharmaceutical Equivalence against the Azomax suspension 200mg/5ml by M/s Novartis Pharma.
	Analytical method validation/verification of product	Not submitted
STABILITY STUDY DATA		
Manufacturer of API	M/s Hebei Guolong Pharmaceutical Co, Ltd., No 9 Xingye street, Shiiazhuang Economic and Technological Development Zone, Hebei Province, China Tel: 0086-575-82736468 Fax: 0086-575-82735575	

API Lot No.	210507019		
Description of Pack (Container closure system)	White to off-white granular powder filled in amber color glass bottle, with white Aluminium cap, is packed in a printed unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	16-01-2021	16-01-2021	16-01-2021
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.15 – 1.5.20	Commitments not submitted	Firm has submitted commitments as per form 5-F
1.6.5	Submit valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	***GMP certificate is not submitted***
2.3.R.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which

<table>
<tr><td></td><td>data is provided in Module 3 section 3.2.P.8.3></td><td>stability studies data is provided in Module 3 section 3.2.P.8.3></td></tr>
<tr><td>3.2.S.4.1. - 3.2.S.4.2</td><td>• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.
• Submit signed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug product manufacturer is required.
• Justify the declared potency of drug substance on COA as it is given on dried basis while in pharmacopeia it is given on anhydrous basis?</td><td>• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is not submitted
• Firm have submitted analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug product manufacturer.
• The firm submitted that potency of API has been calculated on anhydrous basis, whereas the term “on dried basis” was inadvertently mentioned considering it a broader term</td></tr>
<tr><td>3.2.S.4.3</td><td>Analytical Method Verification studies of drug substance(s) for specificity study by the Drug Product manufacturer shall be submitted.</td><td>No reply submitted</td></tr>
<tr><td>3.2.S.4.4</td><td>Batch number of submitted batch analysis by drug product manufacturer (201507019) is different from the batch number submitted by drug substance manufacturer given in batch analysis (210507019)</td><td>The firm have again submitted same COA of drug substance provided by drug substance manufacturer and drug product manufacturer having different batch number and no clarification is provided.</td></tr>
<tr><td>3.2.S.5</td><td>COA of primary standard including source and lot number is submitted. Clarify whether the same reference standard is used by the drug substance manufacturer or drug product manufacturer?</td><td>Firm has submitted COA of primary reference standard and stated that the same is used by drug product manufacturer.</td></tr>
<tr><td>3.2.P.2.1.1</td><td>Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table><tr><td>Applied product</td><td>ZITHROMAX for oral suspension USFDA</td></tr><tr><td>Azithromycin as dihydrate</td><td>Azithromycin as dihydrate</td></tr><tr><td>Sucrose (Extra Fine)</td><td>Sucrose</td></tr><tr><td>Mannitol</td><td>Hydroxypropyl cellulose</td></tr><tr><td>Xanthan gum</td><td>Xanthan gum</td></tr><tr><td>Trisodium phosphate anhydrous</td><td>Sodium phosphate, tribasic, anhydrous</td></tr></table></td><td>• The excipients used in the applied formulation are complying with current pharmacopeial monograph. These excipients are pharmaceutically inert substance and we have used these excipients below the IIG limit of FDA orange book as well as we have done extensive analysis of the product after formulation and found satisfactory result of the assay.
• Also, we have done stability study during development stage and found satisfactory result of the product. So, we can conclude that these excipients are not incompatible with API.</td></tr>
</table>

	Colloidal anhydrous silica (Aerosil 200)	FD&C Red #40; spray dried artificial cherry, creme de vanilla, and banana flavors	
	Sodium benzoate		
	Tutti Frutti powder (PDF 245)		
3.2.P.2.2.1	• In Description of formulation development, you have submitted manufacturing outline. In manufacturing outline, you have mentioned Sodium hydroxy methyl benzoate and sodium propyl hydroxy benzoate, Saccharine sodium, citric acid monohydrate, glycerin, maltitol sodium, strawberry flavor which are not part of applied formulation, clarify? • Furthermore, you have submitted manufacturing outline for liquid suspension while the applied product is dry suspension, clarify?		The firm have submitted corrected composition table and manufacturing outline.
3.2.P.3.2	In batch formula the amount of azithromycin is mentioned without considering the hydrated form clarify?		The firm have submitted revised batch formula and stated that dihydrate will be adjusted by actual potency (on as is basis) given by QC.
3.2.P.5.1	The USP monograph for azithromycin suspension has given the test for dissolution while you have not mentioned the dissolution test in specification, clarify?		The firm submitted that they followed USP-37 monograph of azithromycin oral suspension which did not include dissolution test. The firm further submitted that now they have included dissolution test in specifications and had also performed it on recent time point of long-term stability studies. The firm have submitted revised specifications.
3.2.P.5.2	Submit detailed signed analytical procedures used for testing the drug product shall be provided.		Firm have submitted analytical procedures used for testing of drug product
3.2.P.5.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.		Firm have submitted Analytical Method Verification studies. ***However, results of repeatability (method precision) is not submitted***
3.2.P.5.4	You have not performed dissolution test as per USP monograph of the applied product, clarify?		Reply submitted as above in section 3.2.P.5.1
3.2.P.8	• The results of assay of Batch #01, Batch #02, Batch #03 mentioned in COA of accelerated and real time stability study is different from the assay result given in raw data sheet • Two different method used for sample preparation mentioned in submitted raw data sheet of Batch #T01, clarify?		• The firm submitted that there had been an erroneous drafting error in stability sheets, corrected stability summary sheets are submitted again. ***Further it is submitted that dissolution test results at initial time point, 3rd month time point and 6th month time point of real time and accelerated stability study were given***

	• The results of stability study data of all the three batches at real time and accelerated conditions given in raw data sheet and chromatogram reflects the same value for all the three batches, clarify?	***in stability summary sheets which were neither included in specifications and not performed previously.*** • ***No clarification is submitted*** • ***No clarification is submitted. The submitted raw data sheets reflect that same standard peak area value has been applied for the calculation of Assay results at all time points of stability studies for all three batches.***
	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import). • Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• ***No document/details are submitted*** • ***No document/details are submitted*** • ***No document/details are submitted***

Decision: Deferred for following:

- **Submission of valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.**
- **Submission of Copies of the Drug substance specifications and analytical procedures used for testing of the Drug substance by Drug substance manufacturer.**
- **Submission of results of specificity test in Analytical Method Verification studies of drug substance performed by the Drug Product manufacturer.**
- **Clarification since Batch number of drug substance mentioned in batch analysis by drug product manufacturer (201507019) is different from the batch number mentioned by drug substance manufacturer given in batch analysis (210507019)**
- **Submission of results of repeatability (method precision) test in method verification studies for drug product**
- **Clarification since results of dissolution test were included at initial time point, 3rd month time point and 6th month time point of real time and accelerated stability study in stability summary sheets which were neither included in specifications and not performed previously.**
- **Clarification for considering same standard peak area value for the calculation of Assay results at all-time points of stability studies for all three batches.**
- **Submission of documents for the procurement of API with approval from DRAP (in case of import).**
- **Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).**

383.	Name, address of Applicant / Marketing Authorization Holder	M/s, Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s, Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 30255; dated 05/11/2021
	Details of fee submitted	PKR 30,000/-: dated 27/10/2021
	The proposed proprietary name / brand name	Emeton Injection 4mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Ondansetron (as ondansetron HCl Dihydrate)……..4mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) Antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran 2mg base/ml injection USFDA Approved **Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons****
	For generic drugs (me-too status)	Zofran Injection 4mg/2ml by M/s GSK (Reg#052259)
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSS DC, Industrial Estate, Doddaballapur, Banglore, Karnataka, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ON130001, ON130002, ON130003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed Pharmaceutical Equivalence studies against the Zofran injection by M/s GSK
	Analytical method validation/verification of product	Method verification studies have submitted.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals No D-47 to D-50, C-62 and C-63, KSS DC, Industrial Estate, Doddaballapur, Banglore, Karnataka, India		
API Lot No.	AOND-18006		
Description of Pack (Container closure system)	Colorless liquid filled in ***2ml / 5cc clear glass vial*** labeled and packed in standard unit carton (1 x 1'c) and leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T1/21	T2/21	T3/21
Batch Size	2000 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	01-2021	01-2021	01-2021
No. of Batches	03		

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

Section	Observations	Response
1.5.15 – 1.5.20	Commitments not submitted	Firm has submitted commitments as per form 5-F
1.6.5	Submit valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	***GMP certificate is not submitted***
2.3.R.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4.1. - 3.2.S.4.2	Submit signed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer.	Firm have submitted analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer. ***However, analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug substance manufacturer is not submitted.***
3.2.S.4.3	Clarify whether the Analytical Method Verification studies of drug substance have been performed by drugs substance manufacturer or drug product manufacturer	***No clarification is submitted***
3.2.S.6	Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component and other information on the container closure system(s) (e.g. suitability studies) may be submitted.	***No details submitted***
3.2.S.7	The submitted stability study is performed by M/s CTX Lifesciences while the manufacturer of drug substance is Anugraha Chemicals, clarification is required?	***No clarification is submitted***
3.2.P.1	You have not performed the tests of identification, bacterial endotoxin test and particulate matter in pharmaceutical equivalence, justify?	***No justification is submitted***
3.2.p.3.3.	Submit the flowchart of manufacturing outline since the submitted manufacturing outline is not clearly visible.	***No reply submitted***
3.2.P.5.1	• You have not mentioned the tests of identification, bacterial endotoxin test and particulate matter, justify? • Revise your specifications in line with USP specifications along with submission of applicable fee	***No justification is submitted***
3.2.P.5.3	Analytical Method Verification studies of drug product is same as that of drug substance. Clarification is required	***No clarification is submitted***
3.2.P.7	Specify the container closure system of your product including details	***No details are submitted***

	whether ampoule or vial, filled volume and type of glass, since both ampoule and vials and different volumes have been mentioned in different sections	
3.2.P.8.3	• The stability batches have been manufactured on 01-2021 while the stability chromatograms are acquired in 2019, justify? • COA of 3rd month stability study data not submitted? • The ph values given in stability data sheet and raw data sheet is different at all time point? • COA and raw data sheet at 6th month time point is not submitted	• ***No justification is submitted*** • ***COA of 3rd month stability study data not submitted*** • ***No clarification is submitted*** • Firm has submitted raw data sheet at 6th month time point. ***However, COA at 6th month time point is still not submitted***
	• Audit trail reports on product testing is not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import). • Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated)	***No document/record is submitted***
	• In submitted reply the BMR shows that batch size is 1500 ampoule, while raw data sheet shows 2000 ampoule	

Decision: Deferred for following:

- **Submission of valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.**
- **Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer**
- **Clarification is required since the submitted stability study is performed by M/s CTX Lifesciences while the manufacturer of drug substance is Anugraha Chemicals.**
- **Justification for not including the tests of identification, bacterial endotoxin test and particulate matter in product specifications.**
- **Clarification for submission of same Analytical Method Verification studies for drug product as that of drug substance.**
- **Specify the container closure system of your product including details whether ampoule or vial, filled volume and type of glass, since both ampoule and vials and different volumes have been mentioned in different sections**
- **Justification since the stability batches have been manufactured on 01-2021 while the stability chromatograms are acquired in 2019.**
- **Clarification since the pH values given in stability data sheet and raw data sheet is different at all-time point.**
- **Submission of COA and raw data sheet at 6th month time point.**
- **Submission of documents for the procurement of API with approval from DRAP (in case of import).**
- **Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)**

384.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13411; dated 02/06/2022
	Details of fee submitted	PKR 30,000/-: dated 27/05/2022
	The proposed proprietary name / brand name	Carazole 30mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Lansoprazole as enteric coated pellets (8.5%)……..30mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PREVACID (15mg, 30mg) delayed-release capsules, USFDA approved
	For generic drugs (me-too status)	Caralans 30mg capsule by M/s Caraway Pharmaceuticals (Reg#50809)
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

		Batches: (LPS0129, LPS0134, LPS0141)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Caralans 30mg capsule by Caraway Pharmaceuticals by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is Caralans 30mg capsule by Caraway Pharmaceuticals in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591		
API Lot No.	LPS0382		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 capsules	2500 capsules	2500 capsules
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	06-12-2021	06-12-2021	06-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	No document submitted

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

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Submit valid GMP certificate of the Drug Substance manufacturer	• The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm have submitted Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3
3.2.S.4.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug Product manufacturer is required." • Drug substance manufacturer have claimed USP specifications while monograph for lansoprazole enteric coated pellets are not available in USP., clarification is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Firm have submitted Copies of analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug Product manufacturer. ***However, Copies of the Drug substance specifications by Drug Product manufacturer is not submitted.*** • The firm submitted that API manufacturer claimed and followed USP specifications because Lansoprazole pellets are delayed release and ready to fill in capsule. • Firm have submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance
3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	• Firm have submitted results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including	• ***No justification submitted*** • Fir submitted that study conducted we me-too product due to unavailability of innovator product

	the tests recommended by USP monograph (uniformity of dosage units, loss on drying). • Justification is required since pharmaceutical equivalence and CDP studies have not been conducted against the innovator product. • A minimum of three time-points should be included for CDP, the time-points for both reference (comparator) and test product being the same as per WHO guidelines while you have performed at only one time points i.e. 15 min, justification is required	• The firm has submitted CDP considering multiple time points for both reference (comparator) and test product. CDP has been performed against the same brand that is Caralans 30mg capsule by Caraway Pharmaceuticals in Acid media (pH 1.0-1.2), acetate buffer (pH 5.5) & Phosphate Buffer (pH 6.8).
3.2.P.5	• Justification is required since the submitted specification does not include tests for uniformity of dosage units and loss on drying as recommended by USP. • Justification shall be submitted as the concentration and method of sample and standard solution preparation in assay test is different than that recommended by USP. • Justification is required since drug product manufacturer have proposed 20µl injection volume in chromatographic conditions in assay test instead of 10µl as recommended by USP. • Results of Analytical method verification studies of drug product performed by drug product manufacturer including specificity, repeatability (method precision) and accuracy shall be submitted	• The firm has submitted revised specifications and included tests for uniformity of dosage units and loss on drying as recommended by USP. • The firm have submitted revised method of sample and standard solution preparation in assay test having same concentration of both standard and sample solution. • The firm submitted that writing of 20µl injection volume instead of 10µl injection volume in chromatographic conditions in assay was a human error/typing mistake • Firm have submitted results of Analytical method verification studies of drug product performed by drug product manufacturer including specificity, repeatability (method precision) and accuracy.
3.2.P.8	• Justification is required as 6th month stability study is performed at 04-05-2022 while trial batches are manufactured at 12-2021 before due time (01 month before) of all batches as depicted from raw data sheet and chromatograms at real time and accelerated conditions • COA of the stability batches throughout the stability study is not submitted • Test of uniformity of dosage unit has not been performed at the time of batch release, justify? • Submit documents for the procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	• The firm submitted that 6th month stability study was conducted as realized the provided study was 5th month. The firm has submitted stability study at 6th month time point • ***COA of the stability batches throughout the stability study is not submitted*** • The firm submitted that content uniformity was conducted at the time of batch release but not mentioned in COA of the product. The firm requested to consider the COA of the product submitted now. ***However, the firm have not submitted COA of the product*** • Firm have not submitted documents for the procurement of API • Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted • Compliance record of HPLC software 21CFR & audit trail reports on product testing is not submitted.

Decision: Deferred for following:

- **Submission of Copies of the Drug substance specifications by Drug product manufacturer**
- **Submission of justification as the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph i.e., uniformity of dosage units, loss on drying.**
- **Submission of COA of the stability batches throughout the stability study**
- **Submission of record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)**

385.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19659; dated 05/07/2022
	Details of fee submitted	PKR 30,000/-: dated 21/06/2022
	The proposed proprietary name / brand name	Caraconazole 100mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Itraconazole as enteric coated pellets……100mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	***PPI***
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sporanox 100mg capsule USFDA Approved
	For generic drugs (me-too status)	Rolac 100mg capsule by M/s Sami Pharmaceuticals, (Reg#024491)
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 06 months 06 months real time stability of two batches ICZ1464, ICZ1465 is submitted while three months real time stability study of one batch ICZ1466 is submitted. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Only 03 months accelerated stability study data of batch ICZ1466 is submitted. Batches: (ICZ1464, ICZ1465, ICZ1466)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand POLAC 100mg capsule by SAMI Pharmaceuticals by performing quality tests (Assay). CDP has been performed against the same POLAC 100mg capsule by SAMI Pharmaceuticals in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and in Acid media (0.1N HCl with 0.25% w/v SLS).
	Analytical method validation/verification of product	Not submitted.

STABILITY STUDY DATA			
Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591		
API Lot No.	ICZ1498		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003

Batch Size	2500 capsules	2500 capsules	2500 capsules
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	13-12-2021	13-12-2021	13-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	No document submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm have submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• The applied product contains immediate release pellets while you have applied enteric coated pellets, clarify	• The firm submitted that itraconazole pellets are immediate release while enteric coated pellets was written by mistake and now rectified. The firm submitted revise label as: Each Capsule contains: Itraconazole 22.0% IR pellets equivalent to Itraconazole ……100mg
1.5.5	• You have stated that itraconazole belongs to PPI. Indicate correct Pharmacological class of the API (drug substance) with proper reference.	• The firm have revised Pharmacological class of the API (drug substance) as Antifungal agent
1.6.5	• Submit valid GMP certificate of the Drug Substance manufacturer	• The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm have submitted Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3
3.2.S.4	• Copies of the Drug substance specifications and analytical	• Firm have submitted Copies of analytical procedures used for routine

	procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug Product manufacturer is required." • Drug substance manufacturer have claimed USP specifications while monograph for Itraconazole IR coated pellets are not available in USP., clarification is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Results of dissolution studies given in batch analysis in only 0.1N HCl without SLS, while drug substance manufacturer uses 0.25% w/v SLS in 0.1N HCl., clarification is required	testing of the Drug substance / Active Pharmaceutical Ingredient by Drug Product manufacturer. ***However, Copies of the Drug substance specifications by Drug Product manufacturer is not submitted.*** • The firm submitted that API manufacturer claimed and followed USP specifications because Itraconazole pellets are ready to fill in capsule. • Firm have submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance • ***No clarification is submitted***
3.2.S.7	• Stability study data of drug substance till proposed shelf life shall be submitted	• No reply submitted
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph (uniformity of dosage units, dissolution, identification). • A minimum of three time-points should be included for CDP, the time-points for both reference (comparator) and test product being the same as per WHO guidelines while you have performed at only one time points i.e. 15 min, justification is required • As per WHO guideline surfactants should be avoided in comparative dissolution testing while you have used surfactant in CDP, clarify? • Justification is required since pharmaceutical equivalence and CDP studies have not been conducted against the innovator product. • Similarity factor (F2) of the resulting comparative dissolution profiles should be calculated • The brand name of Comparator product mentioned in pharmaceutical equivalence and CDP studies is Polac 100mg capsule while the brand name of product as per available database is rolac 100mg capsule, clarification is required	• ***No justification submitted*** • Fir submitted that study conducted we me-too product due to unavailability of innovator product • The firm has submitted CDP considering multiple time points for both reference (comparator) and test product. CDP has been performed against the POLAC 100mg capsule by SAMI Pharmaceuticals in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) • ***No justification is submitted*** • Similarity factor (F2) of the resulting comparative dissolution profiles is not provided • ***No clarification is submitted***
3.2.P.5	• Detailed analytical procedures used for testing of the drug product shall be provided.	• Firm has submitted analytical procedures used for testing of the drug product

	• Results of Analytical method verification studies of drug product performed by drug product manufacturer including specificity, repeatability (method precision) and accuracy shall be submitted	• Firm have submitted results of Analytical method verification studies of drug product performed by drug product manufacturer including specificity, repeatability (method precision) and accuracy.
3.2.P.8	• Manufacturing date of pellets as per submitted COA of drug substance manufacturer is 22-12-2021 and release date as per COA is 10-01-2022 while manufacturing of applied product is 12-2021. Justification is required • COA of the stability batches throughout the stability study is not submitted • Test of uniformity of dosage unit has not been performed at the time of batch release, justify? • Submit documents for the procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	• The firm submitted that COA of drug substance was not of the material received and was replaced but unfortunately submitted with the dossier. • ***COA of the stability batches throughout the stability study is not submitted*** • ***No justification is submitted*** • ***Firm has not submitted documents for the procurement of API*** • ***Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted*** • ***Compliance record of HPLC software 21CFR & audit trail reports on product testing is not submitted.***

Decision: Deferred for following:

- **Submission of Copies of the Drug substance specifications by Drug product manufacturer**
- **Submission of clarification since results of dissolution studies for drug substance (pellets) given in batch analysis in only 0.1N HCl without SLS, while drug substance manufacturer uses 0.25% w/v SLS in 0.1N HCl.**
- **Submission of Stability study data of drug substance till proposed shelf life as the submitted stability data is till 06th months.**
- **Submission of justification as the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph.**
- **Submission of justification for using surfactant in CDP studies which is not recommended as per WHO guideline.**
- **Submission of COA of the stability batches throughout the stability study**
- **Submission of justification for not performing test of uniformity of dosage unit at the time of batch release.**
- **Submission of record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)**

Case No. 04: New cases for registration of Human Drugs on Form 5F (Import)

386.	Name, address of Applicant / Importer	M/s AMGOMED., Office # 4, First Floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Pakistan
	Details of Drug Sale License of importer	**License No:** DSL-002-ICT/2013 **Address:** M/s Amgomed office # 4, First floor Ghausia Plaza, Main Jinnah Avenue Blue area Islamabad **Address of Godown:** Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. **Validity:** 30-01-2022 **Status:** Drug Sale License by way of Whole Sale

	Name and address of marketing authorization holder (abroad)	PT Fonko International Pharmaceuticals Address: Kawasan Industri Jababeka II, JI. Industri Selatan V, Blok PP No.7, Cikarang Selatan, Bekasi, Jawa Barat - Indonesia
	Name, address of manufacturer(s)	**Manufacturer & Product License Holder**: Name: PT Fonko International Pharmaceuticals Address: Kawasan Industri Jababeka II, JI. Industri Selatan V, Blok PP No.7, Cikarang Selatan, Bekasi, Jawa Barat - Indonesia Telephone: +62 21 29566111 Fax: +62 21 29566011
	Name of exporting country	Indonesia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted legalized CoPP Certificate No. RG.01.05.32.321.05.21.2804 dated 13-05-2021 issued by BADAN PENGAWAS OBAT DAN MAKANAN. (National Agency of drug and Food Control) Indonesia for FONDRONIC (ZOLEDRONIC ACID) Concentrate for Solution for Infusion; 1 vial /5 mL; The COPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 2 years. **The name of importing country on CoPP is mentioned as Pakistan.**
	Details of letter of authorization / sole agency agreement	Firm has submitted original letter of Authorization dated 28th April, 2021 from M/s PT Fonko International Pharmaceuticals Indonesia. The firm M/s PT Fonko International Pharmaceuticals Indonesia appoint and authorizes M/s Glorious Dexa Singapore PTE. LTD 80 Robin son Road#17-20, Singapore 068898 an exclusive marketer and distributor of Fonko to appoint M/s AMGOMED., Office # 4, First Floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Pakistan as distributor of product Fondronic Concentrate for solution for infusion (Zoledronic Acid 4mg/5ml) in Pakistan and to submit application of drug registration in Drug Regulatory Authority of Pakistan. M/s PT Fonko International Pharmaceuticals Indonesia is the manufacturer and product license holder of the product in Indonesia.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26800: dated 28 -09 -2021
	Details of fee submitted	PKR 150,000/-: 16-09-2021 (Slip#71027968991)

	The proposed proprietary name / brand name	FONDRONIC 4mg/5ml Concentrate for Solution for Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Zoledronic acid monohydrate equivalent to zoledronic acid…….4 mg
	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion
	Pharmacotherapeutic Group of (API)	Bisphosphonates WHO ATC code: M05BA
	Reference to Finished product specifications	Not provided
	Proposed Pack size	1 vial x 5ml
	Proposed unit price	AS PER SRO
	The status in reference regulatory authorities	Zoledronic acid Fresenius Kabi 4 mg/5 ml concentrate for solution for infusion by M/s Fresenius Kabi Australia Pvt Ltd MHRA Approved ZOMETA (4mg/5ml) solution for injection USFDA Approved
	For generic drugs (me-too status)	Macdronic Injection 4mg/5ml by M/s Macter International (Reg# 079757)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Hetero Labs Limited., S. No. 10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District-502319, Telangana, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25 ºC ± 2ºC / 60 ± 5% RH for 60 months while accelerated stability study is conducted at 40 ºC ± 2ºC / 75 ± 5% RH for 06 months. Batch No# (ZL0030410, ZL0040410, ZL0010215)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted results of pharmaceutical equivalence against the product Zoledronic acid 4mg/5ml injection manufactured by M/s Hetero Labs Ltd and reference product which is Zometa injection 4 mg/5 mL, manufactured by Novartis Pharma Stein AG, Switzerland.
	Analytical method validation/verification of product	***Firm has submitted analytical method verification studies instead of analytical method validation for the applied product by performing test for specificity, accuracy, precision and solution stability***
	Container closure system of the drug product	The final container closure system used for Zoledronic acid concentrate for solution for infusion 4 mg/5 mL is 5 mL round clear cyclic olefin polymer (COP) plastic vial with 20 mm neck covered by 20 mm grey chlorobutyl fluorotec rubber stopper and sealed by aluminium and 20 mm red flip off.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40○C ±2oC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30oC ±2oC / 75% ± 5% RH. The real time stability study data is till 36 months for 3 batches.

Batch No.	**Mfg. date**	**Initiation date**
K-10462-00-F-PSC-1	Dec 2015	Dec 2015
K-10462-00-F-PSC-2	February 2016	April 2016
D0004	February 2017	February 2017

Remarks of Evaluator [XI]:

Section	**Observations**	**Response**
1.3.4	Submit copy of Valid Drug Sale License	The firm have submitted valid copy of drug sale license. The details are given below. **License No:** DSL-002-ICT/2013 **Address:** M/s Amgomed office No.4, 1st floor, Ghousia Plaza, Main Jinnah Avenue Blue area Islamabad **Address of Godown:** Office No. 5, First floor Rose-I plaza, I-8 Markaz Islamabad. **Validity:** 30-01-2022 **Renewed upto:** 30-01-2024 **Status:** Drug Sale License by way of Whole Sale
1.5.6	Mention the reference specifications of the finished product	Firm has submitted that Finished product specification is not listed in any compendium, therefore finished product specification was developed in house based on general chapter of European Pharmacopeia and hetero Labs Limited quality documents. The specification of finished product from Hetero Labs Limited is submitted
1.5.15-1.5.20	Commitments must be submitted by applicant (marketing authorization Holder) instead of manufacturer	Firm has submitted commitments as per the guidance document

1.6.5	Submit valid GMP certificate of drug substance manufacturer	Firm has submitted Drug License No. 25/MD/AP/97/B/R dated 23/11/2021 valid upto 21/11/2024 of M/s Hetero Labs Limited., S. No. 10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District-502319, Telangana, India
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Specifications and analytical procedure from PT Fonko International Pharmaceutical is submitted • The drug product manufacturer has submitted method verification studies for drug substance.
3.2.P.5	Results of Analytical method validation of drug product performed by drug product manufacturer including linearity, range and robustness shall be submitted	We hereby declare that this product is a technology transfer from Hetero Labs Limited and we adopted the same analytical procedure from them. We performed verification (based on USP 43<1226> Verification of Compendial Procedures) to validate the process in our laboratory. Hereby we would like to inform you: • For the assay procedure; intermediate precision, linearity, range and robustness tests were not performed as part of method verification as the same as are available in the method validation document (tech transfer document protocol no. AD6/AMV/P/12-046 and report document no. AD6/AMV/R/12-046. • For the related compounds procedure; accuracy, intermediate precision, limit of detection, linearity, range and robustness tests were not performed as part of method verification as the same as are available in the method validation document (tech transfer document protocol no. AD6/AMV/P/12-039 and report document no. AD6/AMV/R/12-039.

Decision: Approved with innovators specifications and as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

- **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

387.	Name, address of Applicant / Importer	M/s AMB HK ENTERPRISES (PVT) LTD., 2nd Floor, Plaza 60, Commercial, Block-K, Phase 1 DHA Lahore
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor, Plaza 60, Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24-02-2023. **Status:** License to sell drugs as distributor **Renewal:** NA

	Name and address of marketing authorization holder (abroad)	Hainan Brilliant Pharmaceutical Co., Ltd., 4 Medicine Valley, No. 1 Road, Haikou National High-tech Development Zone, Haikou City, China.
	Name, address of manufacturer(s)	Hainan Brilliant Pharmaceutical Co., Ltd., No. 4 Fist Road of Yaogu, Haikou National High-tech Industrial Development Zone, Haikou City, Hainan Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 20210060) dated 16-04-2021 issued by Hainan Provincial Medical Products Administration China for azithromycin for injection 0.5g. The CoPP confirms that the product strength is not in market of exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 15-04-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of agency agreement from M/s Hainan Brilliant Pharmaceutical Co., Ltd. The letter species that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Lahore** to register their products in Pakistan. The authorization letter is valid till 22-10-2024. The letter issued for azithromycin for injection 500mg.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26416: 23-09-2021
	Details of fee submitted	PKR 150,000/-: 29-06-2021 (Slip#306286776760)
	The proposed proprietary name / brand name	**ZITHROBAR INJECTION 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Active ingredient Name; Azithromycin Strength; 500mg
	Pharmaceutical form of applied drug	Powder for injection (Lyophillized)
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Macrolides
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	Rs 215/-

	The status in reference regulatory authorities	ZITHROMAX 500mg for injection USFDA Approved.
	For generic drugs (me-too status)	Azineu 500mg Injection by M/s Neutro Pharma (Reg# 097656)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Zhejiang Goubang Pharmaceutical Co., Ltd., No.6, Weiwu Road, Hangzhou Gulf Shangyu Economic & Technological Development Zone, Zhejiang China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ºC ± 2ºC / 75 ± 5% RH for 24 months while accelerated stability study is conducted at 40 ºC ± 2ºC / 75 ± 5% RH for 06 months. Batch No# (103-180306-11, 103-180307-11, 103-180308-11)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence against the innovator product Zithromax 500mg Inj by performing quality test (pH, Water Content, Bacterial Endotoxin, Sterility, Visible particle, Assay).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Injection Vial made of Middle Borosilicate Glass tubing (10ml) with brominated rubber stopper and caps made of aluminium-polypropylene combinations
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at

		40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. ***The real time stability study data is submitted for 18 months only.***

Batch No.	Mfg. date	Batch size
1905051	05.05.2019	5000 vials
1905091	09.05.2019	5000 vials
1905131	13.05.2019	5000 vials

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.3	The submitted CoPP confirms that the product strength is not in market of exporting country, clarify?	The firm submitted clarification from Director Quality Department, Hainan Brilliant Pharmaceutical Co., Ltd and stated that the azithromycin for injection 0.5g has been marketed in China (Exporting Country). The person responsible for the application of CoPP misunderstood he exporting country was referring to Pakistan thus ticked wrong column in CoPP.
1.5.2	Strength of Active ingredient shall be stated clearly. In case API is in the form of salt / hydrate, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.	The firm have submitted the label claim as: Each vial contains: Azithromycin as dihydrate…….500mg
1.5.15-1.5.20	Commitments must be submitted by applicant (marketing authorization Holder) instead of manufacturer	The firm has submitted commitments as per guidance document
1.6.5	Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm has submitted GMP certificate No. ZJ20190170 in the name of M/s Zhejiang Goubang Pharmaceutical Co., Ltd., No.6, Weiwu Road, Hangzhou Gulf Shangyu Economic & Technological Development Zone, Zhejiang China valid upto 29/11/2024
3.2.S.4	• Copies of the analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer and drug product manufacturer is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Copies of the analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer and drug product manufacturer is submitted. • Analytical Method Verification studies including specificity, linearity range, precision, accuracy, solution stability and robustness performed by the Drug Product manufacturer for drug substance(s) is submitted.
3.2.P.5	• You have applied for USP specifications. However, the limits for assay test given in specifications is not according to USP monograph, clarify? ***Release specifications; (103%-113%)*** ***Shelf life specifications; (101%-115%)*** ***Monograph: (90%-110%)*** • Test for uniformity of dosage units is not included in specifications recommended by USP • The chromatographic conditions of the analytical method are different from the USP monograph (mobile phase, injection volume, lambda,	The firm submitted that specification applied for azithromycin for injection 0.5g is in-house specification rather than USP, so there is difference in specification, test items and chromatographic conditions compared to USP.

3.2.P.8	• Submit stability study data of drug product till the claimed shelf life	The firm have submitted stability study data of three batches. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH for 24 months

Decision: Deferred for following points:

- **clarification for not complying USP specifications of finished drug product as USP specifications are more stringent to in-house specifications.**
- **Whether manufacturing has been done via lyophilization or dry powder filling and relevant manufacturing facility there of.**

388.	Name, address of Applicant / Importer	M/s AMB HK ENTERPRISES (PVT) LTD., 2nd Floor, Plaza 60, Commercial, Block-K, Phase 1 DHA Lahore
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor, Plaza 60, Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24-02-2023. **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyang Road, Yiyuan County, Shandong Province, China
	Name, address of manufacturer(s)	Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyang Road, Yiyuan County, Shandong Province, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 201910005) issued by Yiyuan Market Supervision Administration of P.R China for vitamin C Injection 500mg/5ml. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP is valid till 23-10-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Registration & Distribution agreement dated 29-08-2019 from M/s Reyoung Pharmaceutical Co., Ltd. The letter species that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Lahore** to register and develop pharmaceutical market of their products in Pakistan. The authorization letter remains valid for 05 years from the date of product registration certificate. The letter issued for vitamin C injection 500mg/5ml in addition to 08 other product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging

		☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26417: 23-09-2021
	Details of fee submitted	PKR 150,000/-: 26-05-2021 (Slip#1272535835)
	The proposed proprietary name / brand name	VITA-C INJECTION 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Ascorbic Acid 10.0% w/v.
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Ascorbic acid (vitamin C), plain ATC Code: A11GA
	Reference to Finished product specifications	BP
	Proposed Pack size	5ml type I glass ampoule; 10 ampoules/tray,10trays/boxes*12boxes/carton
	Proposed unit price	PKR 21.35/unit
	The status in reference regulatory authorities	Ascorbic Acid Injection BPC 500mg/5ml MHRA Approved.
	For generic drugs (me-too status)	Ascorbic Acid Injection 500mg by M/s Enam Ellahie Karachi (Reg# '004784)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	CSPC Weisheng Pharmaceutical (Shijiazhuang) Co., Ltd., No. 236 Huanghe Street High-tech Industrial Development Zone, Shijiazhuang City, Hebei Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ºC ± 2ºC / 65 ± 5% RH for 36 months while accelerated stability study is conducted at 40 ºC ± 2ºC / 75 ± 5% RH for 06 months. Batch No# (1150452001, 1150452002, 1150452003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study of drug product.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence against the reference product acido Ascorbico labesfal injection 500mg by performing quality test (identification, Acidity, Oxalic acid, Bacterial Endotoxin, Sterility, Visible particle, content of ascorbic acid).
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	USP type-I glass ampoule (5ml)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH. The real time stability study data is submitted for 36 months only.

Batch No.	Mfg. date	Date of initiation
173212044	03-2017	03-2017
173212045	03-2017	03-2017
173212046	03-2017	03-2017

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.3	Submit valid CoPP certificate for the applied product	Firm has submitted original legalized CoPP certificate (No. 2021120004) issued by Yiyuan Market Supervision Administration of P.R China for vitamin C Injection 500mg/5ml. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP is valid till 06-12-2023.
1.5.2	Strength of Active ingredient shall be stated clearly. In case API is in the form of salt / hydrate, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.	Each 5ml ampoule contains: Ascorbic acid …….500mg
1.5.15-1.5.20	Commitments must be submitted by applicant (marketing authorization Holder) instead of manufacturer	Firm has submitted commitments as per guidance document
1.6.5	• The drug substance manufacturer as per section 3.2.S.2 is CSPC Weisheng Pharmaceutical (Shijiazhuang) Co., Ltd., No. 236 Huanghe Street High-tech Industrial Development Zone, Shijiazhuang City, Hebei Province, China while you have written Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyang Road, Yiyuan County, Shandong Province, China in this section, clarify? • Submit GMP certificate of drug substance manufacturer	• The firm submitted that drug substance manufacturer is CSPC Weisheng Pharmaceutical (Shijiazhuang) Co., Ltd., No. 236 Huanghe Street High-tech Industrial Development Zone, Shijiazhuang City, Hebei Province, China and it was a mistake at their end by writing wrong name of manufacturer • The firm has submitted copy of GMP certificate No. HE20150023 in the name of M/s CSPC Weisheng Pharmaceutical (Shijiazhuang) Co., Ltd., No. 236 Huanghe Street High-tech Industrial Development Zone, Shijiazhuang, China valid upto 14/02/2020
3.2.S.4	• The specifications and analytical procedure of the drug substance provided is according to Chinese pharmacopeia while the product is available in BP. Justify that specification of drug substance are	• The firm submitted that specifications of drug substance provided according to Chinese pharmacopeia is from API manufacturer, the finished product manufacturer test the API according to BP. Now the finished product

	equivalent to BP specifications (the number and limits of tests are within range of BP.) • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	manufacturer have supplemented the standards for raw material • Firm have submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer. • The firm submitted that vitamin C produced by CSPC WEISHENG is tested in strict accordance with Chinese Pharmacopoeia, ***there is not need to verify the analytical method.***
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided	The firm stated that the primary reference standard is from EDQM and government sector, hence no COA is submitted.
3.2.P.2.1.1	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to reference product. • Applied product: Ascorbic acid, Sodium bicarbonate, Sodium metabisulfite, cysteine HCl, Disodium edetate, water for injection • Reference product: Ascorbic Acid, Sodium Bicarbonate, Sodium Metabisulphite Hydrochloric acid Water for injections • Details of reference / comparator product including batch numbers, manufacturing & expiry date in pharmaceutical equivalence are required to be provided • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?	• Firm have submitted Compatibility studies of the Drug Substance(s) with excipients and observe the colour change and change in ph during the study • Firm have provided details of reference / comparator product including batch numbers, expiry date in pharmaceutical equivalence • The firm submitted that at that time innovator product has been delisted

Decision: Deferred for submission of following documents:

- **Pharmaceutical equivalence against innovator drug ptoduct.**
- **Verification studies of analytical method of drug substance by drug product manufacturer.**

389.	Name, address of Applicant / Importer	M/s AMB HK ENTERPRISES (PVT) LTD., 2nd Floor, Plaza 60, Commercial, Block-K, Phase 1 DHA Lahore
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor, Plaza 60, Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24-02-2023. **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	JARI Pharmaceutical Co., Ltd., 18 Zhenhua Road, Lianyungang City, Jiangsu P.R China, 222006
	Name, address of manufacturer(s)	JARI Pharmaceutical Co., Ltd., 18 Zhenhua Road, Lianyungang City, Jiangsu P.R China, 222006
	Name of exporting country	China

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. JS20210117) dated 04-02-2021 issued by Jiangsu drug Administration China for oxaliplatin for injection 50mg. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP is valid till 03-02-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of foreign agency agreement dated February 02, 2021 in which M/s JARI Pharmaceutical Co., Ltd., referred to as the manufacturer grants M/s Liaoning Hongyan Pharmaceutical Co., Ltd exclusive right to export and sell all product (Ten (10) in number) including oxaliplatin for injection 50mg in Pakistan. M/s Liaoning Hongyan Pharmaceutical Co., Ltd referred to as exporter grants **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** exclusive rights to sell and distribute the products from M/s Liaoning Hongyan Pharmaceutical Co., Ltd in Pakistan which has an understanding with M/s JARI Pharmaceutical Co., Ltd., The agreement shall be effective from date of execution and shall remain in force for five (05) years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ ***Domestic sale*** ☐ ***Export sale*** ☒ ***Domestic and Export sales***
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 24847: 08-09-2021
	Details of fee submitted	PKR 150,000/-: 26-05-2021 (Slip#076513194992)
	The proposed proprietary name / brand name	Runplatin Injection 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Active ingredient Name: Oxaliplatin Strength; 50mg
	Pharmaceutical form of applied drug	Lyophilized powder for Injection
	Pharmacotherapeutic Group of (API)	Not applicable
	Reference to Finished product specifications	Chinese Pharmacopeia
	Proposed Pack size	20 ml
	Proposed unit price	PKR 7700/-
	The status in reference regulatory authorities	GN-OXALIPLATIN oxaliplatin 50 mg powder for injection vial TGA Approved.
	For generic drugs (me-too status)	Oxaliplatino Varifarma Lyophilized Powder for Injection 50mg by M/s Medinet Pharmaceuticals (Reg# '095884)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Kunming Guiyan Pharmaceutical Co., Ltd., Room 706, Integrated Business Building in Jinding Science & technology zone, 690#, Xuefu Road, Kuming, Yunnan, China, 650033
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25 ºC ± 2ºC / 60 ± 5% RH for 36 months of following batches. Batch No# (L20150613, L20161010, L20161106) Accelerated stability study is conducted at 40 ºC ± 2ºC / 75 ± 5% RH for 06 months of following batches. Batch No# (L20090107, L20090108, L20090109)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Analytical method validation/verification of product	Not submitted
	Container closure system of the drug product	Medium boron silicon glass tube-type vial (20ml), pharmaceutical bromobutyl rubber stopper and caps made of aluminium plastic combination
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH. The real time stability study data is submitted for 36 months only.

Batch No.	**Mfg. date**	**Date of initiation**
17101817	02-2017	03-2017
17102517	02-2017	03-2017
18051217	02-2017	03-2017

Remarks of Evaluator [XI]:

Section	**Observations**	**Response**
1.4.1	Applicant needs to clarify whether the applied product (drug product) is intended for sale in domestic market or both for	The firm have submitted that applied product is intended both for domestic and export sale

	domestic and export market. There is no column for overseas sale	
1.5.2	Strength of Active ingredient shall be stated clearly. In case API is in the form of salt / hydrate, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.	Each vial contains: Oxaliplatin …….50mg
1.5.5	Indicate Pharmacological class of the API (drug substance) with proper reference. Also, state the WHO ATC code for each distinct therapeutic indication.	Firm have indicated Pharmacological class of the API (drug substance). Third generation platinum anticancer drug ATC Code; L01XA03
1.5.15-1.5.20	Commitments must be submitted by applicant (marketing authorization Holder) instead of manufacturer	Firm have submitted commitment as per guidance document
1.6.5	• The drug substance manufacturer as per section 3.2.S.2 is Kunming Guiyan Pharmaceutical Co., Ltd., Room 706, Integrated Business Building in Jinding Science & technology zone, 690#, Xuefu Road, Kuming, Yunnan, China, 650033 while you have written JARI Pharmaceutical Co., Ltd., 18 Zhenhua Road, Lianyungang City, Jiangsu P.R China, 222006 China in this section, clarify? • Submit GMP certificate of drug substance manufacturer	• The firm submitted that drug substance manufacturer is Kunming Guiyan Pharmaceutical Co., Ltd., Room 706, Integrated Business Building in Jinding Science & technology zone, 690#, Xuefu Road, Kuming, Yunnan, China, 650033 and it was a mistake at their end by writing wrong name of manufacturer • The firm has submitted copy of GMP certificate No. YN20170040 in the name of M/s Kunming Guiyan Pharmaceutical Co., Ltd., Inside Kunming Precious Metals Research Institute, No. 988, Keji Road, High-tech Development Zone, Kunming City China valid upto 24/12/202
3.2.S.4	• Test for content of platinum is not included in specifications although recommended by USP • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both drug substance manufacturer and Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Test results of Batch analysis are submitted as per USP specifications. However, the specifications of applied product are given according to EP, clarify?	• We refer to EP, content of platinum is not included in EP specifications • Firm have submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient Drug Product manufacturer. ***Copies of Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is not submitted*** • ***Analytical Method Verification studies is not submitted as per requirement*** • The firm submitted batch analysis of drug substance as per EP.
3.2.S.8	Justify why stability study data of different batches of drug substance conducted at accelerated and real time conditions is submitted.	Firm have submitted long term stability study data at 25 ºC ± 2ºC / 60 ± 5% RH for 36 months of same batches for which stability study data at accelerated conditions is submitted. Batch No# (L20090107, L20090108, L20090109)
3.2.P.2	• Reference product has used lactose monohydrate while you have use lactose	• The firm submitted that through conversion lactose content is consistent with reference product

	in composition of applied product, clarify? • Submit Pharmaceutical equivalence of the applied product against the innovator product	• ***The firm submitted pharmaceutical equivalence of applied product with product of Jiangsu Hengrui Pharmaceutical Co., Ltd***
3.2.P.5	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	Firm have submitted Analytical Method Verification studies including specificity, and repeatability (method precision). ***However, results of accuracy test is still not submitted***
The firm has applied for Chinese pharmacopeia specifications while the monograph for the applied product is available in USP and the limits of tests of applied product are in line with USP specifications.		

Decision: Deferred for following:

- **Submission of Pharmaceutical equivalence studies against the innovator product.**
- **Submission of Copies of Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer.**
- **Submission of Analytical Method Verification studies for drug substance**
- **Submission of results of accuracy test in method verification studies for drug product**

Case No.05; Registration applications of Human Drugs on Form 5 (Local)

390.	Name and address of manufacture / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan ***Contract Manufactured by:*** M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan"
	Brand Name + Dosage Form and Strength	Tazdim 1000mg dry powder Injection IV/IM
	Composition	Each Vial Contains: Ceftazidime Sodium eq to Ceftazidime……1000mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11378 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Cephalosporine
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftazidime 1g powder for solution for injection/infusion MHRA Approved
	Me-too-status	Kefamin Injection 1g IM/IV by M/s Maxitech Pharma (Reg#097036)
	GMP Status	The firm M/s Semos Pharmaceuticals was inspected on 02-09-2021 and conclusion of inspection was: Based on the stated observations, facts and keeping in view the attitude of the firm towards continuous improvements their current GMP compliance level is rated as GOOD. The firm M/s Perfect Pharma was inspected on 22/09/2021 & 08/10/2021 and conclusion of inspection was: Overall, the firm showed satisfactory improvements as per cGMP requirements.
	Remark of the Evaluator [XI]	• The firm have submitted revised form 5 and corrected the salt and hydrated form of ceftazidime in label claim and master formulation ***along with submission of Rs. 75000/- on*** deposit slip#6872949424. The revised label claim is as under: Each Vial Contains: Ceftazidime (Ceftazidime as pentahydrate)……1000mg

		• Form 5 is submitted by the applicant i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted list of 06 approved sections of applicant. i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted that they never applied before any product for registration on contract manufacturing • The firm submitted unsigned copy of contract manufacturing agreement between M/s Perfect Pharma Pvt Ltd and /s Semos Pharmaceuticals Pvt Ltd.
	Decision: Approved with following label claim: **Each Vial Contains:** **Ceftazidime (Ceftazidime as pentahydrate)……..…1000mg** **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan"**	
391.	Name and address of manufacture / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan ***Contract Manufactured by:*** M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan"
	Brand Name + Dosage Form and Strength	Tazdim Dry Powder Injection 250mg IV/IM
	Composition	Each Vial Contains: Ceftazidime Sodium eq to Ceftazidime……250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11379 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Cephalosporine
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftazidime 250mg powder for solution for injection MHRA Approved
	Me-too-status	Kefamin Injection 250mg IM/IV by M/s Maxitech Pharma (Reg#097037)
	GMP Status	The firm M/s Semos Pharmaceuticals was inspected on 02-09-2021 and conclusion of inspection was: Based on the stated observations, facts and keeping in view the attitude of the firm towards continuous improvements their current GMP compliance level is rated as GOOD. The firm M/s Perfect Pharma was inspected on 22/09/2021 & 08/10/2021 and conclusion of inspection was: Overall, the firm showed satisfactory improvements as per cGMP requirements.
	Remark of the Evaluator [XI]	• The firm have submitted revised form 5 and corrected the salt and hydrated form of ceftazidime in label claim and master formulation ***along with submission of Rs. 75000/- on*** deposit slip#008346330. The revised label claim is as under: Each Vial Contains: Ceftazidime (Ceftazidime as pentahydrate)……250mg • Form 5 is submitted by the applicant i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted list of 06 approved sections of applicant. i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted that they never applied before any product for registration on contract manufacturing • The firm submitted unsigned copy of contract manufacturing agreement between M/s Perfect Pharma Pvt Ltd and /s Semos Pharmaceuticals Pvt Ltd.

	Decision: Approved with following label claim: **Each Vial Contains:** **Ceftazidime (Ceftazidime as pentahydrate)……..…250mg** **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan"**	
392.	Name and address of manufacture / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan ***Contract Manufactured by:*** M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form and Strength	Tazdim Dry powder Injection 500mg IV/IM
	Composition	Each Vial Contains: Ceftazidime Sodium Eq To Ceftazidime…….500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11377 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Cephalosporine
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftazidime 500mg powder for solution for injection MHRA Approved
	Me-too-status	Kefamin Injection 500mg IM/IV by M/s Maxitech Pharma (Reg#097038)
	GMP Status	The firm M/s Semos Pharmaceuticals was inspected on 02-09-2021 and conclusion of inspection was: Based on the stated observations, facts and keeping in view the attitude of the firm towards continuous improvements their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have submitted revised form 5 and corrected the salt and hydrated form of ceftazidime in label claim and master formulation ***along with submission of Rs. 75000/- on*** deposit slip#98891560. The revised label claim is as under: Each Vial Contains: Ceftazidime (Ceftazidime as pentahydrate)……..…500mg • Form 5 is submitted by the applicant i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted list of 06 approved sections of applicant. i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted that they never applied before any product for registration on contract manufacturing • The firm submitted unsigned copy of contract manufacturing agreement between M/s Perfect Pharma Pvt Ltd and /s Semos Pharmaceuticals Pvt Ltd.
	Decision: Approved with following label claim: **Each Vial Contains:** **Ceftazidime (Ceftazidime as pentahydrate)……..…500mg** **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan"**	

Case No. 06: Deferred cases:

a. Deferred cases of Human Drugs on form 5

393.	Name and address of manufacture / Applicant	M/s M.S. Enterprises Ltd., 3.5km Raiwind Kot Radha kishan Road, kasur
	Brand Name + Dosage Form and Strength	Pakcip 200mg/100ml Infusion

	Composition	Each ml Contains: Ciprofloxacin……...2mg
	Dairy No. date of R &I fee	Form-5 Dy.No 16542 dated 04-05-2018 Rs.20,000/- Dated 03-05-2018 *Duplicate Dossier, R&I Verified*
	Pharmacological Group	Fluoroquinolones
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	100ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin 2mg/ml solution for infusion (MHRA approved)
	Me-too-status	Riget 200Mg/100ml Infusion by Saydon Pharmaceutical Industries (Pvt) Ltd (Reg#36936)
	GMP Status	The firm was inspected on 22.01.2020 and conclusion of inspection was: Keeping in view the observations and after going through the documentation and overall operations, the panel was of the opinion that the firm M/s M.S. Enterprises Ltd., Lahore was GMP compliant on the day of inspection
	Previous Remark of Evaluator [XI]	• The firm submitted copy of fee challan No. 0776351 dated 03.05.2018 submitted for the applied product. • The firm have revised the label claim and mentioned the correct salt form of ciprofloxacin along with submission of Rs. 5000/- on deposit slip No#2103609 dated 04.05.2021. The revised label claim is as under: Each 100ml Vial Contains: Ciprofloxacin Lactate 254mg eq. to Ciprofloxacin …200mg • Clarification is required as in manufacturing outline filling in polypropylene bags is mentioned while in type of container PE 100ml bottle is mentioned
	Previous Decision (307-DRB)	• Deferred for clarification for type of primary packaging container of the applied formulation
	Evaluation by PEC	• The firm submitted that solution is filtered close to filling point of the machine. After filtration the solution is filled into Low Density Polyethylene (LDPE) 100ml Plastic Bottles and then these bottles are packed in PE (polyethylene) bags. However, the reference formulation is packed in PVC bag contained in a polypropylene/polyester aluminium/polyester pouch.
	Decision: Deferred for deliberation regarding formulation and salt form of ciprofloxacin.	
394.	Name and address of manufacture / Applicant	M/s M.S. Enterprises Ltd., 3.5km Raiwind Kot Radha kishan Road, kasur
	Brand Name + Dosage Form and Strength	Paklev 500mg/100ml Infusion
	Composition	Levofloxacin Hemihydrate……..512mg Sodium Chloride……..0.9g
	Dairy No. date of R &I fee	Form-5 Dy.No 16541 dated 04-05-2018 Rs.20,000/- 03-05-2018 *Duplicate Dossier, R&I Verified*
	Pharmacological Group	Fluoroquinolones
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	100ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	The firm was inspected on 22.01.2020 and conclusion of inspection was: Keeping in view the observations and after going through the documentation and overall operations, the panel was of the opinion that

		the firm M/s M.S. Enterprises Ltd., Lahore was GMP compliant on the day of inspection
	Previous Remark of Evaluator [XI]	• The firm submitted copy of fee challan No. 0776355 dated 03.05.2018 submitted for the applied product. • Undertaking at the end of form 5 is missing • The firm have revised the label claim along with submission of Rs. 5000/- on deposit slip No#2103611 dated 04.05.2021. The revised label claim is as under: Each 100ml Vial Contains: Levofloxacin Hemihydrate 512.42mg eq. to Levofloxacin ……500mg • The firm provided evidence of approval of product in RRA. Levofloxacin 5mg/mL Solution for infusion MHRA approved • The firm provided evidence of approval of me-too. Liv-Mark Infusion 500mg/100ml by M/s Medimarker's Pharmaceuticals (Reg#100410) • Clarification is required as in manufacturing outline filling in polypropylene bags is mentioned while in type of container PE 100ml bottle is mentioned
	Previous Decision (307-DRB)	Deferred for following: • Submission of undertaking at the end of form 5 • Clarification for type of primary packaging container of the applied formulation
	Evaluation by PEC	• The firm submitted undertaking at the end of form 5 • The firm submitted that solution is filtered close to filling point of the machine. After filtration the solution is filled into Low Density Polyethylene (LDPE) 100ml Plastic Bottles and then these bottles are packed in PE (polyethylene) bags.
	Decision: Approved with JP specifications and following label claim: **Each 100ml Vial Contains:** **Levofloxacin Hemihydrate 512.42mg eq. to Levofloxacin ……500mg** • **Firm shall submit the fee of Rs. 25,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), and product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
395.	Name and address of manufacture / Applicant	M/s M.S. Enterprises Ltd., 3.5km Raiwind Kot Radha kishan Road, kasur
	Brand Name + Dosage Form and Strength	Pakzole 500mg/100ml Infusion
	Composition	Metronidazole……..…5mg/ml
	Dairy No. date of R &I fee	Form-5 Dy.No 16544 dated 04-05-2018 Rs.20,000/- Dated 03-05-2018 *Duplicate Dossier, R&I Verified*
	Pharmacological Group	Imidazole derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	100ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Metronidazole 500mg/100mL Solution for infusion MHRA approved
	Me-too-status	Anagyl 5mg/ml IV Infusion by M/s Iqra Pharmaceuticals (Reg# 097712)
	GMP Status	The firm was inspected on 22.01.2020 and conclusion of inspection was: Keeping in view the observations and after going through the documentation and overall operations, the panel was of the opinion that the firm M/s M.S. Enterprises Ltd., Lahore was GMP compliant on the day of inspection

	Previous Remark of Evaluator [XI]	• The firm submitted copy of fee challan No. 0776353 dated 03.05.2018 submitted for the applied product. • Undertaking at the end of form 5 is missing • The firm have revised the label claim along with submission of Rs. 5000/- on deposit slip No#2103612 dated 04.05.2021. The revised label claim is as under: Each 100ml Vial Contains: Metronidazole…….500mg • Clarification is required as in manufacturing outline filling in polypropylene bags is mentioned while in type of container PE 100ml bottle is mentioned
	Previous Decision (307-DRB)	Deferred for following: • Submission of undertaking at the end of form 5 • Clarification for type of primary packaging container of the applied formulation
	Evaluation by PEC	• The firm submitted undertaking at the end of form 5 • The firm submitted that solution is filtered close to filling point of the machine. After filtration the solution is filled into Low Density Polyethylene (LDPE) 100ml Plastic Bottles and then these bottles are packed in PE (polyethylene) bags.
	Decision: Approved with following label claim: **Each 100ml Vial Contains:** **Metronidazole…….500mg** • **Firm shall submit the fee of Rs. 25,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
396.	Name and address of manufacture / Applicant	M/s M.S. Enterprises Ltd., 3.5km Raiwind Kot Radha kishan Road, kasur
	Brand Name + Dosage Form and Strength	Moxin 400mg/250ml Infusion
	Composition	Each 250ml vial Contains: Moxifloxacin HCl 436mg eq. to Moxifloxacin…….400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 16546 dated 04-05-2018 Rs.20,000/- Dated 03-05-2018 *Duplicate Dossier, R&I Verified*
	Pharmacological Group	Fluoroquinolones
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Moxifloxacin 400mg/250mL Solution for infusion MHRA Approved
	Me-too-status	M-Floxsel Infusion 400mg/250ml by M/s Pharmasol (Pvt) Ltd (Reg# 100857)
	GMP Status	The firm was inspected on 22.01.2020 and conclusion of inspection was: Keeping in view the observations and after going through the documentation and overall operations, the panel was of the opinion that the firm M/s M.S. Enterprises Ltd., Lahore was GMP compliant on the day of inspection
	Previous Remark of Evaluator [XI]	• The firm submitted copy of fee challan No. 0776356 dated 03.05.2018 submitted for the applied product. • Master formulation and manufacturing method not submitted • Clarification is required as in type of container PE 100ml bottle is mentioned
	Previous Decision (307-DRB)	Deferred for following: • Submission of master formulation and manufacturing method of the applied formulation

		• Clarification for type of primary packaging container of the applied formulation
	Evaluation by PEC	• The firm submitted that solution is filtered close to filling point of the machine. After filtration the solution is filled into Low Density Polyethylene (LDPE) 100ml Plastic Bottles and then these bottles are packed in PE (polyethylene) bags. • Master formulation and manufacturing method of the applied formulation is still not submitted
	Decision: Approved with innovator's specifications • **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	

397.	Name and address of manufacture / Applicant	M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan
	Brand Name+Dosage Form+Strength	Recuro UD Eye Drops (solution)
	Composition	Each ml Contains: Carboxymethylcellulose Sodium…..…5mg Glycerin……10mg Polysorbate 80……...5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10357 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Lubricating and moisturizing comfort solution
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	0.4ml (30's ampoules), 0.4ml (60's ampoules); As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	Firm was inspected on 03-04-2019 and conclusion of inspection was: Overall cGMP is found at acceptable level and the management is committed for continual improvement and has assured further cGMP compliance.
	Previous Remark of Evaluator [XI]	• The firm provided evidence of RRA. Refresh Optive Advanced Lubricant Eye Drops OTC product by M/s Allergan Inc, (Daily Med) • The firm provided evidence of me-too. Recuro Drops 0.5% by M/s Hudson Pharma (Reg#091123). However, the provided me-too is not as per applied product (contain only carboxymethyl cellulose 5mg).
	Previous Decision (307-DRB)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	• The firm again provided evidence of same me-too. Recuro Drops 0.5% by M/s Hudson Pharma (Reg#091123). However, the provided me-too is not as per applied product (contain only carboxymethyl cellulose 5mg). • The firm itself revised the formulation and revised the label claim along with submission of Rs 30000/- on deposit SlipNo.991599286662. The revised label claim is as under: Each ml Contains: Carboxymethylcellulose Sodium…..…5mg Evidence of RRA: Celluvisc 0.5 %w/v eye drops solution (Ireland approved) Pack size: 30's (0.4ml LDPE container), 60's (0.4ml LDPE container) • The same molecule is already registered with the firm

		• The firm submitted revised master formulation of already applied product containing all three APIs.
	Previous Decision (313-DRB)	• Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm OR submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.
	Evaluation by PEC	• The firm submitted that they have already registered RECURO (Carboxymethylcellulose) Eye Drops 5mg in multi-dose container of 15ml with the registration No. 091123. • The firm further stated that they want the same composition in unit dose container of 0.4mlx30's, but mistakenly we had added two of its excipients (glycerin & polysorbate) in composition of registration application. For the same we have submitted the fee of standardization of formulation as per international reference and locally available product and requested to accept the clarification.
	Previous Decision (316-DRB)	• Deferred for clarification regarding manufacturing of applied product in the proposed manufacturing facility "Plastic ampoules (BFS) section.
	Evaluation by PEC	• The firm submitted that our product is a unit dose formulation of 0.4ml that is available in plastic ampoules as per the innovator product " Celluvisc 0.5% w/v eye drops solution". • The firm further submitted that we have Rommelag 360M filling machine (BFS) which has the capacity to fill the volume from 0.1ml to 40ml, and the firm also submitted latest GMP report for evidence. • It is to submit that carboxy methyl cellulose sodium 0.5% eye drops is a stability molecule
	Decision:Registration Board deliberated the matter in detail and observed that the applied formulation is already registered in Pakistan in 15ml fill volume as multi-dose (LDPE) container and instant application is with same formulation and container closure system and thus stability study is not required being a generic product applied on Form 5. Therefore, the Board decided to approve the product with innovator's Specifications.	
398.	Name and address of manufacture / Applicant	M/s Wilson's Pharmaceuticals., 387-388, I-9, Industrial Area, Islamabad
	Brand Name + Dosage Form+ Strength	Wilsonide Plus Dry Powder Inhaler 400/12 mcg capsule
	Composition	Each DPI Capsule Contains: Budesonide……400mcg Formoterol fumarate dihydrate…….12mcg
	Dairy No. date of R &I fee	Form-5 Dy.No 6952 dated 19-02-2019 Rs.20,000/- 19-2-2019
	Pharmacological Group	Glucocorticosteroid/Selective β2 adrenoceptor agonist
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Symbicort Turbohaler 400 micrograms / 12 micrograms / inhalation, inhalation powder (MHRA approved)
	Me-too-status	Formiget DPI Capsule 400mcg+12mcg by Getz Pharma (Reg#098828)
	GMP Status	The firm was inspected on 24-01-2018 and conclusion of inspection was: "Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."

	Remark of the Evaluator [XI]	
	Remarks	**Response by the firm**
	• As per 290th decision of Registration board, provide evidence of separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend.	The firm submitted approved layout plan for manufacturing of DPI and panel constituted letter for onsite inspection but have no approved section/manufacturing facility at present. Moreover the firm submitted a list of equipments that will be used in manufacturing including eqipments for DPI mixing and DPI filling.
	• As per 290th decision of Registration board, provide evidence of equipments for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia.	The firm informed that equipments for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" have been procured and are available for testing.
	• The reference formulation have mentioned the hydrated form (dihydrate) of Formoterol fumarate in the label claim while you have not mentioned the hydrated form. Revise the label claim as per reference formulation mentioning the hydrated form along with submission of applicable fee.	The firm have revised the label claim mentioning the hydrated form of Formoterol fumarate in the label claim
	• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.	The firm have submitted commitment for performing the stability study as per Requirements of Registration Board decision of 293rd meeting.
	Previous Decision (296-DRB)	Deferred for confirmation of required manufacturing facility "Dry Powder inhaler" section with manufacturing and testing equiments for applied formulation.
	Evaluation by PEC	• The firm have submitted letter No. F. 1-19/92-Lic (Pt-I) dated 15th September 2021 issued by secretary Central Licensing Board confirming the presence of Dry Powder Inhaler Capsule (Steroidal) section • Moreover, the firm submitted a list of equipments that will be used in manufacturing and testing for applied formulation. • Stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting is not submitted.
	Decision: Deferred for Submission of Stability study data as per guidelines approved in 293rd meeting of Registration Board.	
399.	Name and address of manufacture / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan ***Contract Manufactured by:*** M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form and Strength	Draxil 125mg/5ml Suspension
	Composition	Each 5ml Contains: Cefadroxil as Monohydrate……125mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11368 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Cephalosporins
	Type of form	Form 5
	Finished product specifications	Manufacturer' s Specifications
	Pack size and Demand Price	90ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Ozix Dry Powder Suspension 125mg/5ml by M/s Maxitech Pharma (Reg#097182)
	GMP Status	The firm M/s Semos Pharmaceuticals was inspected on 02-09-2021 and conclusion of inspection was:

		Based on the stated observations, facts and keeping in view the attitude of the firm towards continuous improvements their current GMP compliance level is rated as GOOD. The firm M/s Perfect Pharma was inspected on 22/09/2021 & 08/10/2021 and conclusion of inspection was: Overall, the firm showed satisfactory improvements as per cGMP requirements.
	Previous Remark of the Evaluator [XI]	• The firm did not provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting • Form 5 is submitted by the applicant i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted list of 06 approved sections of applicant. i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted that they never applied before any product for registration on contract manufacturing • The firm did not submit list of products applied for contract manufacturing. • The firm submitted contract manufacturing agreement between M/s Perfect Pharma and M/s Semos Pharmaceuticals • The firm have revised specifications from manufacturer's specifications to USP specifications without submission of applicable fee.
	Previous Decision (316-DRB)	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Submission of fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
	Evaluation by PEC	• The firm have submitted fee of Rs. 7,500 vide deposit slip#50708779569 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • Biodroxil 125mg/5ml powder for oral suspension AGES Austria approved
	Decision: Approved with USP specifications Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan"	
400.	Name and address of manufacture / Applicant	M/s Perfect Pharma Pvt Ltd. 5-Km, Manga Road, Raiwind, Lahore, Pakistan ***Contract Manufactured by:*** M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form and Strength	Cefra 125mg/5ml Suspension
	Composition	Each 5ml Contains: Cephradine as Monohydrate……..…125mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11363 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Cefra Dry Suspension 125mg by M/s Max Pharmaceuticals, (Reg#075406)

	GMP Status	The firm M/s Semos Pharmaceuticals was inspected on 02-09-2021 and conclusion of inspection was: Based on the stated observations, facts and keeping in view the attitude of the firm towards continuous improvements their current GMP compliance level is rated as GOOD. The firm M/s Perfect Pharma was inspected on 22/09/2021 & 08/10/2021 and conclusion of inspection was: Overall, the firm showed satisfactory improvements as per cGMP requirements.
	Previous Remark of the Evaluator [XI]	• The firm did not provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Form 5 is submitted by the applicant i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted list of 06 approved sections of applicant. i.e. M/s Perfect Pharma Pvt Ltd • The firm submitted that they never applied before any product for registration on contract manufacturing • The firm did not submit list of products applied for contract manufacturing. • The firm submitted contract manufacturing agreement between M/s Perfect Pharma and M/s Semos Pharmaceuticals • The firm have revised the specifications from manufacturer's specifications to USP specifications along with submission of Rs. 7500/- on deposit slip No#49340178993.
	Previous Decision (316-DRB)	• Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC	• The firm provided evidence of applied product in RRA. Velosef 125mg/5ml for oral suspension USFDA approved. ***However, the applied product is discontinued***
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
401.	Name and address of manufacture / Applicant	M/s Paramount Pharmaceuticals., Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad ***Contract Manufactured By:*** M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form and Strength	Colistacin 1 M IU Injection
	Composition	Each Vial Contains: Colistimethate Sodium eq. to Colistimethate Lyophilized Powder…….1MIU
	Dairy No. date of R &I fee	Form-5 Dy.No 13002 dated 05-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	other antibacterials (polymyxins)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection MHRA Approved
	Me-too-status	Colicraft Injection by Biolabs (Pvt) Ltd. (Reg# 082407)
	GMP Status	The firm M/s Paramount Pharmaceuticals was inspected on 08-02-2019 and conclusion of inspection was: During review of approval of above-mentioned sections/manufacturing facilities, it was assessed that following two sections needs regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General)

		The firm has applied for the regularization of same in Licensing Division. Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose. Certificate of GMP Issued to M/s Bio Labs Pvt on 25-05-2019.
	Previous Remark of the Evaluator [XI]	• The firm have submitted differential fee Rs. 55000/- on deposit slip No# 873385180685 for contract manufacturing. • Form 5 is submitted by the applicant i.e. M/s Paramount Pharmaceuticals duly signed by the applicant • The firm submitted list of 08 approved sections of applicant. i.e. M/s Paramount Pharmaceuticals • The firm submitted list of 11 products registered/approved on contract manufacturing in name of applicant. i.e. M/s Paramount Pharmaceuticals • The firm submitted list of 14 products applied for contract manufacturing by the applicant. • The firm submitted copy of contract manufacturing agreement between M/s Paramount Pharmaceuticals and M/s Bio Labs Pvt Ltd • The firm have not revised the label claim as per reference formulation without considering the salt factor. The submitted label claim is as under: Each Vial Contains: Colistimethate Sodium eq. to Colistimethate …….1MIU Lyophilized Powder
	Previous Decision (316-DRB)	Deferred for following: • Confirmation of method of manufacturing of applied formulation whether by lyophilization or otherwise. • Further deliberation for revision of label claim as per reference formulation and pharmacopoeial specifications.
	Evaluation by PEC	• The firm have submitted revised form 5 and revised label claim as per reference formulation without submission of applicable fee. The revised label claim is as under: Each Vial Contains: Colistimethate Sodium …….1MIU (Lyophilized Powder) • Firm has submitted revised form 5 and revised manufacturing method and stated that the product is manufactured by lyophilization. • Registration Board in its 293rd meeting held on 06-08th January 2020 allowed contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: Dry Suspension (Cephalosporin) Capsule (Cephalosporin) Dry vial injectable (Cephalosporin) lyophilized vial injectable (General)
	Decision: Registration Board deferred for following reasons: • **Submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.** • **Firm shall submit fee of Rs.7,500/- for correction/pre-approval change in the method of manufacture, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

	• **Submission of GMP audit report for both M/s Paramount Pharmaceuticals and M/s Bio Labs Pvt Ltd from QA&LT Division, valid within last three years**	
402.	Name and address of manufacture / Applicant	M/s Paramount Pharmaceuticals., Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad ***Contract Manufactured By:*** M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form and Strength	Paracin 1g Injection
	Composition	Each Vial Contains: Vancomycin HCl eq. to Vancomycin……1g (lyophilized powder)
	Dairy No. date of R &I fee	Form-5 Dy.No 13004 dated 05-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Glycopeptide antibacterials
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vancomycin 1g Powder for Solution for Infusion MHRA approved
	Me-too-status	Vancozon 1000mg Injection by M/s Horizon Healthcare (Reg#099988)
	GMP Status	The firm M/s Paramount Pharmaceuticals was inspected on 08-02-2019 and conclusion of inspection was: During review of approval of above mentioned sections/manufacturing facilities, it was assessed that following two sections needs regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose. Certificate of GMP Issued to M/s Bio Labs Pvt on 25-05-2019.
	Previous Remark of the Evaluator [XI]	• The firm have submitted differential fee Rs. 55000/- on deposit slip No# 1837746820 for contract manufacturing. • Form 5 is submitted by the applicant i.e. M/s Paramount Pharmaceuticals duly signed by the applicant • The firm submitted list of 08 approved sections of applicant. i.e. M/s Paramount Pharmaceuticals • The firm submitted list of 11 products registered/approved on contract manufacturing in name of applicant. i.e. M/s Paramount Pharmaceuticals • The firm submitted list of 14 products applied for contract manufacturing by the applicant. • The firm submitted copy of contract manufacturing agreement between M/s Paramount Pharmaceuticals and M/s Bio Labs Pvt Ltd
	Previous Decision (316-DRB)	• Deferred for confirmation of method of manufacturing of applied formulation as well as of innovator, whether by lyophilization or otherwise.
	Evaluation by PEC	• Firm has submitted revised form 5 and revised manufacturing method and stated that the product is manufactured by lyophilization.
	Decision: Approved.	

	• **Firm shall submit fee of Rs.7,500/- for correction/pre-approval change in the method of manufacture, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Submission of GMP audit report for both M/s Paramount Pharmaceuticals and M/s Bio Labs Pvt Ltd from QA&LT Division, valid within last three years** • **Registration Board in its 293rd meeting held on 06-08th January 2020 allowed contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for** **following sections:** **Dry Suspension (Cephalosporin)** **Capsule (Cephalosporin)** **Dry vial injectable (Cephalosporin)** **lyophilized vial injectable (General)**	
403.	Name and address of manufacture / Applicant	M/s Paramount Pharmaceuticals., Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad ***Contract Manufactured By:*** M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form and Strength	Paracin 500mg Injection
	Composition	Each Vial Contains: Vancomycin HCl eq. to Vancomycin ……500mg (lyophilized powder)
	Dairy No. date of R &I fee	Form-5 Dy.No 13003 dated 05-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Glycopeptide antibacterials
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vancomycin 500mg Powder for Solution for Infusion MHRA approved
	Me-too-status	Vancozon 500mg Injection by M/s Horizon Healthcare (Reg#099987)
	GMP Status	The firm M/s Paramount Pharmaceuticals was inspected on 08-02-2019 and conclusion of inspection was: During review of approval of above mentioned sections/manufacturing facilities, it was assessed that following two sections needs regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose. Certificate of GMP Issued to M/s Bio Labs Pvt on 25-05-2019.
	Previous Remark of the Evaluator [XI]	• The firm have submitted differential fee Rs. 55000/- on deposit slip No# 55914109 for contract manufacturing. • Form 5 is submitted by the applicant i.e. M/s Paramount Pharmaceuticals duly signed by the applicant • The firm submitted list of 08 approved sections of applicant. i.e. M/s Paramount Pharmaceuticals • The firm submitted list of 11 products registered/approved on contract manufacturing in name of applicant. i.e. M/s Paramount Pharmaceuticals • The firm submitted list of 14 products applied for contract manufacturing by the applicant.

		• The firm submitted copy of contract manufacturing agreement between M/s Paramount Pharmaceuticals and M/s Bio Labs Pvt Ltd
	Previous Decision (316-DRB)	• Deferred for confirmation of method of manufacturing of applied formulation as well as of innovator, whether by lyophilization or otherwise.
	Evaluation by PEC	• Firm has submitted revised form 5 and revised manufacturing method and stated that the product is manufactured by lyophilization.
	Decision: Approved. • **Firm shall submit fee of Rs.7,500/- for correction/pre-approval change in the method of manufacture, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Submission of GMP audit report for both M/s Paramount Pharmaceuticals and M/s Bio Labs Pvt Ltd from QA&LT Division, valid within last three years** • **Registration Board in its 293rd meeting held on 06-08th January 2020 allowed contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for** **following sections:** **Dry Suspension (Cephalosporin)** **Capsule (Cephalosporin)** **Dry vial injectable (Cephalosporin)** **lyophilized vial injectable (General)**	

404.	Name and address of manufacture / Applicant	M/s Aulton Pharmaceuticals., Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Aultopride 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride…….50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 24088 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Propulsive
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	1x10's, 1x30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton 50mg film coated tablet (PMDA) Japan Approved
	Me-too-status	Itonext 50mg Tablet by M/s Next Pharmaceutical Products (Reg#095612)
	GMP Status	The firm was inspected on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Previous Remark of the Evaluator [XI]	• The firm have claimed for JP specifications and the official monograph is not available in any pharmacopeia • The firm have not mentioned the salt form of itopride in the label claim. Revise the label claim as per reference formulation mentioning the salt form of itopride along with submission of applicable fee. • The firm did not submit 1st page of form 5 • The firm submitted revised master formulation and removed methylene chloride from formulation
	Previous Decision (307-DRB)	Deferred for following: • Revision of the label claim mentioning the salt form of itopride as per reference formulation along with submission of applicable fee.

		• Submission of 1st page of form 5 as per prescribed format
	Evaluation by PEC	• The firm have revised the label claim and mentioned the salt form of itopride as per reference formulation along with submission of Rs. 7500/- on deposit slip#52202875778. The revised label claim is as under: Each Film Coated Tablet Contains: Itopride hydrochloride…….50mg • Firm have submitted 1st page of form 5 as per prescribed format
	Decision: Approved with innovator's specifications and following label claim: **Each Film Coated Tablet Contains:** **Itopride hydrochloride…….50mg** **Firm shall submit the fee of Rs. 22,500/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
405.	Name and address of manufacture / Applicant	M/s Aulton Pharmaceuticals., Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Diclo injection 75mg
	Composition	Each injection contains: Diclofenac sodium……75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 24089 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	NSAIDs
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	3mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Econac 75mg/3ml Solution for Injection MHRA Approved
	Me-too-status	Difisal 75mg/3ml Injection by M/s Iqra Pharmaceuticals (Reg# 097721)
	GMP Status	The firm was inspected on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Previous Remark of the Evaluator [XI]	• The firm have claimed for USP specifications and the official monograph is not available in any pharmacopeia. • The applied label claim is not as per reference formulation. Revise the label claim as per reference formulation along with submission of applicable fee. • Provide evidence of required manufacturing facility/section approval letter
	Previous Decision (307-DRB)	Deferred for following: • Revision of the label claim as per reference formulation along with submission of applicable fee. • Evidence of required manufacturing facility / section from Licensing Division.
	Evaluation by PEC	• The firm have revised the label claim and mentioned the per reference formulation along with submission of Rs. 7500/- on deposit slip#77164606773. The revised label claim is as under: Each 3ml ampoule contains: Diclofenac sodium……75mg • The firm have submitted cGMP certificate issued on 04-06-2021 based on inspection conducted on 11-12-2020 showing presence of Liquid Injectable general section.
	Decision: Approved with innovator's specifications and following label claim:	

	Each 3ml ampoule contains: **Diclofenac sodium……75mg**	

406.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals., 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Medonac 75mg Tablet
	Composition	Each enteric coated tablet contains: Diclofenac sodium……..75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9946 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	NSAIDS
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	VOLTAREN (25mg, 50mg, 75mg) Delayed Release/ enteric-coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Torelief 75mg Tablet by M/s Maple Pharmaceuticals (Reg.# 058203)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Previous Remark of the Evaluator [XI]	• Revise the 1st page of form 5 as per approved format • Undertaking at the end of form 5 is not signed by the technical persons. • All the details of form 5 submitted are of the wimits pharmaceuticals, clarify?
	Previous Decision (296-DRB)	Deferred for clarification regarding submission of details of M/s Wimits pharmaceuticals while applied product is for Hi-Med Pharmaceuticals
	Evaluation by PEC	• Firm have submitted revised form 5 as per prescribed format and undertaking at the end of form 5 signed by technical persons. • The firm submitted that writing wrong name of company was a typographical error and submitted revised documents.
	Decision: Approved.	

b. Deferred case of Priority Registration of Fludrocortisone tablets

The Drug Regulatory Authority of Pakistan in its 91st meeting held on 4th September 2020, exercising its power under Rule 26 of Drugs (LRA) Rules amended vide SRO 713(I)/2018 dated 8th June, 2018, allowed to submit registration applications on Form 5 / Form 5-A / Form 5-D instead of Form 5F, for Registration of Fludrocortisone tablets in light of approvals granted by the reference regulatory authorities and with the following additional conditions:

i. The applicants can submit their applications till 30-09-2020 and these applications will be considered out of queue.
ii. Registration Board may consider grant of registration and submission of data of product development and 6 months accelerated and 6 months real time stability studies data before sale of product along with other data as may be required.

407.	Name and address of manufacture / Applicant	M/s Pharmix Laboratories Pvt Ltd., 21 Km, Ferozepur Road, Lahore
	Brand Name+Dosage Form+Strength	Flocort 0.1mg Tablet
	Composition	Each Tablet Contains: Fludrocortisone Acetate……0.1mg
	Dairy No. date of R &I fee	Form-5D Dy.No 25619 dated 30-09-2020 Rs.50,000/- 30-09-2020
	Pharmacological Group	Mineralocorticoid
	Type of form	Form 5D
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Fludrocortisone Acetate 0.1mg Tablets MHRA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 13.09.2019 with the following recommendations: The panel of inspector recommends the renewal of M/s Pharmix Laboratories Pvt Ltd. Located at 21 Km, Ferozepur Road, Lahore bearing DML No. 000397 subject to verification of all approved sections by the licensing division, DRAP, Islamabad.
	Previous Remark of the Evaluator [XI]	• The firm have mentioned only generic name of product and does not mentioned the dosage form, strength and brand name of drug on fee challan • ***The firm submitted letter No. F. 1-28/93-Lic issued by secretary central licensing board dated 30-06-2020 confirming the presence of tablet hormonal section and not tablet steroidal section***
	Previous Decision (297-DRB)	• Deferred for evidence of approval of required manufacturing facility for the applied product.
	Evaluation by PEC	• The firm have submitted a letter stating that they are having Steroidal Hormonal section (***on section approval it is mentioned Hormonal section as in 2008 there was no classification***) and having steroidal hormone products like methyl testosterone tablets Registration No#064653 under manufacturing so as we are having approved Steroidal Hormone section, and requested to approve the applied product.
	Decision: Deferred for evidence of approval of required manufacturing facility / section from Licensing Division.	

c. Deferred cases of Human Drugs on form 5F (Import)

408.	Name, address of Applicant / Importer	M/s Biocare Pharmaceutica. Address: 807 Shadman-1, Lahore
	Details of Drug Sale License of importer	License No: 05-352-0063-032069D Address: 807 Shadman-1, District Lahore. Address of Godown: First floor B-C, Street No. 3, Near LGS School, Shah Jamal District Lahore. Validity: 17-04-2022. Status: License to sell drugs as distributor Renewal: N/A. Valid Drug sales License is attached with CTD dossier Module 1.
	Name and address of marketing authorization holder (abroad)	Hainan Hualon Pharmaceutical Co., Ltd Address: - ***Pharmacy*** Valley Three Cross Road No.8, Haikou National Hi-Tech Industrial Development Zone, Hainan Province, China.
	Name, address of manufacturer(s)	Hainan Hualon Pharmaceutical Co., Ltd Address: - Pharmacy Valley Three Cross Road No.8, Haikou National Hi- Tech Industrial Development Zone, Hainan Province, China.
	Name of exporting country	China

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted embassy attested copy of CoPP certificate (No.Hainan20200100) dated 25-11-2020 issued by Hainan Medical Product Administration to M/s Hainan Hualon Pharmaceutical Co., Ltd No. 8, Three Cross Road, Medicine Valley, National Hi-Tech Industrial Development Zone, Haikou, Hainan Province China for Aztreonam for injection 1g. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP is valid till 25-11-2022. Firm has submitted embassy attested copy of GMP certificate No. HI20180041 issued by Hainan Provincial Medical Product Administration to M/s Hainan Hualon Pharmaceutical Co., Ltd No. 8, Three Cross Road, Medicine Valley, National Hi-Tech Industrial Development Zone, Haikou, Hainan Province valid till 18/11/2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of distribution and agency agreement contract signed by both parties Biocare Pharmaceutica & Hainan Hualon Pharmaceutical Co., Ltd. Agreement mention manufacturer Hualon Pharmaceutical appoints M/s Biocare Pharmaceutica to register/market/sell their product Aztreonam 1 gm in Pakistan and is valid for 5 years from the first day of month when distributor receives registration certificate.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 10518: 06-04-2021
	Details of fee submitted	PKR 100,000/-: 11-03-2021
	The proposed proprietary name / brand name	AZTAM, AZOM, AZENOT
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains mixture of Aztreonam and Arginine equivalent to Aztreonam 1.0g
	Pharmaceutical form of applied drug	Sterile powder for injection white or off-white powder or loose cake in 10ml tubular vial, sealed with rubber stopper and aluminium-plastic combination cap.
	Pharmacotherapeutic Group of (API)	Anti-infectives for systemic use-Monobactams ATC code: J01DF01
	Reference to Finished product specifications	USP 39 ***&CP (Chinese Pharmacopeia)***
	Proposed Pack size	1's
	Proposed unit price	Rs 800/- single dose vial

	The status in reference regulatory authorities	Azactam (Aztreonam for injection) 1 gm by M/s Bristol Myers Squibb Co., (USFDA Approved).
	For generic drugs (me-too status)	Azactam (Aztreonam) 1 gm Injection of Squibb (Karachi) (Reg # 009002)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd; Address: No.1, Huanan Yi Road, Changshou, Chongqing, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated study is complete for 3 batches at 40±2°C/75±5%RH (Batch No. Az(Ar)150101V, Az(Ar)150102V, *Az(Ar)150103V).* The real time stability data is conducted at 30±2°C/65±5%RH (Batch No. Az(Ar)150101V, Az(Ar)150102V, *Az(Ar)190101).* The stability study data of two batches is performed till 36 months while stability of one batch (No# Az(Ar)190101) is performed upto 18th months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Comparative Specifications of Test performed with Reference Product Azactam (Aztreonam) 1 gm of Bristol Myers Squibb.
	Analytical method validation/verification of product	Firm has submitted analytical method validation/verification studies for the applied product.
	Container closure system of the drug product	Low Borosilicate tubular vial, sealed with Halogenated butyl rubber stopper, covered by aluminium-plastic combination cap for antibiotic bottle
	Stability study data of drug product, shelf life and storage conditions	• Firm has submitted stability study data of 3 batches of Aztreonam for Injection 1.0g vial. The firm has submitted accelerated stability study data at 40°C ± 2°C / 75% ± 5% RH for 6 months and real time stability study data at 30 °C ±2 °C / 65 % ± 5%RH for 24 months. •

Batch No.	Mfg. Date	Initiation date
20181201	Dec.12, 2018	Dec.12, 2018
20190101	Jan.4, 2019	Jan.4, 2019
20190102	Jan.4, 2019	Jan.4, 2019

Evaluation by PEC [XI]:

Section	Observations	Response
1.3	Provided form 5F is from the manufacturer / Marketing authorization holder side while it should be from the applicant holding the Drug sale license.	New Form 5F duly signed/stamped by Drug Sale License holder Biocare Pharmaceutica is submitted
1.3.4	Provide valid legalized GMP certifcate from the manufacturer as the name and adress of manufacturer in the submitted GMP is different from the one verified from China CFDA website	**Title as per Online Link:** Hainan Hua*ng*lon*g* Pharmaceutical Co., Ltd. **Address:** *No. 8, Sanheng Road, Yaogu*, National High-tech Industrial Development Zone, Haikou, Hainan Province **Title as per submitted GMP:** Hainan Hualon Pharmaceutical Co., Ltd **Address:** *No. 8, Three Cross Road, Medicine Valley*, National Hi-Tech Industrial Development Zone, Haikou, Hainan Province The firm submitted that they have two manufacturing site; 1. Pharmacy Valley Three Cross Road No.8, Haikou National Hi- Tech Industrial Development Zone, Hainan Province 2. Guilinyang Economic Development Area, Haikou Hainan (for tablets). Aztreonam for injection is in 1st manufacturing address.
1.5.6	In Form 5F you have mentioned both USP 39 &CP (Chinese Pharmacopeia) reference for the product under section 1.5.6. specify a particular specification for applied product.	***Manufacturer/In-house quality specifications referenced USP39 and Chinese Pharmacopoeia parameters/limits*** Referencing USP and Chinese Pharmacopoeia, we established our enterprise quality specifications. Our enterprise quality specifications are stringent in which limits or parameters comply with both USP and Chinese Pharmacopoeia reference standard. For the critical items, our enterprise specifications are equivalent to, or even stricter than USP. For example, pH, sterile, water, related substances are equivalent to USP., while bacterial endotoxins and assay are stricter than USP. Below reference is given for DRAP reference.

Comparison of Aztreonam API Quality specifications

Items		ChP2020	USP43	Enterprise quality specification (Mixture of Aztreonam and arginine)
Tests	pH	2.2-2.8	4.7-6.9	4.7-6.9
	Residue on ignition	Not more than 0.1%	Not more than 0.1%	Not more than 0.1%
	Related substances	Single impurity:≤1.5% Sum: ≤3.5%	Open-ring aztreonam and open-ring desulfated aztreonam: ≤1.0%; Aztreonam E-isomer: ≤ 0.5%; Aztreonam ethyl ester: ≤ 1.5%; Any individual unspecified impurity: ≤0.1%; Total impurities: ≤3.0%;	Single impurity:≤1.5% Sum: ≤3.0%
	Sterile	Sterile	Sterile	Sterile
	Water	Not more than 2.0%	Not more than 2.0%	Not more than 1.5%
	Bacterial endotoxins	Less than 0.17EU per 1mg.	Less than 0.17EU per 1mg.	Less than 0.1EU per 1mg.
	Heavy metals	Not more than 10ppm	Not more than 30ppm	Not more than 10ppm
Assay		It contains NLT 93.0% and NMT 103.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on the anhydrous basis.	It contains NLT 92.0% and NMT 105.0% of C13H17N5O8S2, calculated on the anhydrous and solvent-free basis.	It contains NLT 95.0% and NMT 103.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on the anhydrous and arginine-free basis.

*Green is equivalent; Red is stricter.

Comparison of Aztreonam for injection Quality specifications

Items		Enterprise quality specification	ChP2020	USP43
Tests	pH	4.5-7.5	4.5-7.5	4.5-7.5
	Sterile	Sterile	Sterile	Sterile
	Water	Not exceed 2.0%	Not exceed 2.0%	Not exceed 2.0%
	Related substances	Single impurity:≤1.5% Sum: ≤5.0%	Single impurity:≤1.5% Sum: ≤5.0%	/ (Remarks: It has been reflected in the quality standard of API)
	Bacterial endotoxins	Less than 0.15EU per 1mg.	Less than 0.17EU per 1mg.	Less than 0.17EU per 1mg.
Assay		It contains not less than 91.0% and not more than 103.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on the anhydrous and arginine-free basis.	It contains not less than 91.0% and not more than 103.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on the anhydrous and arginine-free basis.	It contains NLT 90.0% and NMT 105.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on the anhydrous and arginine-free basis.
		Each container contains not less than 90.0% and not more than 115.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on basis of the average weight of contents.	Each container contains not less than 90.0% and not more than 115.0% of aztreonam ($C_{13}H_{17}N_5O_8S_2$), calculated on basis of the average weight of contents.	Each container contains NLT 90.0% and NMT 120.0% of the labeled amount of aztreonam ($C_{13}H_{17}N_5O_8S_2$).

*Green is equivalent; Red is stricter.

	Submit valid and original product specific sole agency agreement/ letter of authorization for applied product	Valid notarized product specific Soles agency agreement duly signed/stamped by both Biocare Pharmaceutica & manufacturer Hainan Hualon Pharmaceutical Co., Ltd is submitted.
1.5.15-1.5.19	Commitments must be submitted by applicant (marketing authorization Holder) instead of manufacturer	Commitments is submitted by applicant (marketing authorization Holder)

3.2.S.4.2.2	Chromatographic conditions e.g. mobile phase is not same as mentioned in USP monograph of aztreonam for injection, clarify?	We have separately tested the same batch of aztreonam under chromatographic conditions of Chinese pharmacopoeia and USP. The study shows that, under the chromatographic conditions of Chinese pharmacopoeia, the peak shape of each compound is better than that of USP, and the number of impurities detected and the resolution of each compound are better than those under the USP test methods. Therefore, our mobile phase adopts the chromatographic conditions of Chinese pharmacopoeia.
3.2.S.7.3	Long term stability data of drug substance batch No. Az(Ar)190101 is performed upto 18th months only	The dossier was submitted in the year 2020 and the batch No. Az(Ar)190101 was manufactured in in the year 2019, so we could only submitted 18th months data then and did not submit complete 36th months stability data. Now we submit 24th months stability data No. Az(Ar)190101 and complete 36th months stability data of ***Az(Ar)150103V.***
3.2.S.7.3	Stability study data of one different batch of drug substance is performed at real time and accelerated conditions	At that time, the batch number of three batches of long term stability data which were provided to us by the API manufacturer were Az(Ar)150101V，Az(Ar)150102V，***Az(Ar)190101). We directly quoted these three batches of long-term stability data without careful consideration.*** To reply this point, we asked the API manufacturer to provide us the complete data of ***Az(Ar)150103V.*** The long-term stability data of same batch is submitted
3.2.P.1	Quantity of arginine is not mentioned in composition?	We use mixture of aztreonam and arginine (premixed by API manufacturer). The quantity of aztreonam: arginine is 1:0.78, which is same as the originator (Bristol-Myer Squibb Company USA). So, in one vial there are 1.0g aztreonam and 0.78g arginine
3.2.P.1	Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.	The firm submitted that their product Aztreonam Sterile powder for injection will be supplied to Biocare Pharmaceutica in a pack that only contain Aztreonam Vial without any diluent. ***We are not providing any diluent. Our pack only contains Aztreonam Vial.***
3.2.P.5.2	Chromatographic conditions e.g. mobile phase is not same as mentioned in USP monograph of aztreonam for injection, clarify?	We have separately tested the same batch of aztreonam under chromatographic conditions of Chinese pharmacopoeia and USP. The study shows that, under the chromatographic conditions of Chinese pharmacopoeia, the peak shape of each compound is better than that of USP, and the number of impurities detected and the resolution of each compound are better than those under the USP test methods. Therefore, our mobile phase adopts the chromatographic conditions of Chinese pharmacopoeia. Note that the chromatographic conditions of the injection and its API is the same because the injection is produced by simply filling the API into the bottle without adding any other excipients.

Previous Decision (316-DRB):	Deferred for clarification as the name and address mentioned on submitted GMP is different from the name and address verified from online weblink of the "NMPA" of China.
Evaluation by PEC	The firm submitted that name and address of the manufacturer in weblink of NMPA of China to those submitted in GMP is same upon verification. Difference in address in English version of NMPA weblink might be due to translation error or confusion might be due to shorter version of address given on GMP certificate. In Chinese version of NMPA website, address mention in GMP certificate and on NMPA weblink is same. There is no difference in address. Hence, it is confirmed from our end after verification, name and address mentioned on submitted GMP is same as the name and address given on weblink of NMPA
Decision: Approved with USP specifications and as per Policy for inspection of Manufacturer abroad and verification of local storage facility. • **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

409.	Name and address of manufacture / Applicant	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Pioglet 30mg Tablet
	Composition	Each Tablet Contains: Pioglitazone as HCl…….30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10589 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Thiazolidinediones
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ACTOS (15mg, 30mg, 45mg) tablets USFDA approved
	Me-too-status	Glzone 30mg Tablet by M/s Innvotek Pharmaceuticals, (Reg#099251)
	GMP Status	GMP certificate issued on 25.11.2020 based on inspection conducted on 23.11.2020
	Previous Remark of Evaluator [XI]	• The firm have removed coating composition from master formulation, however the firm did not submit revised manufacturing outline. Furthermore, firm have not adjusted the weight of pioglitazone in master formulation without considering the salt factor
	Previous Decision (316-DRB)	• Deferred for adjustment of the weight of pioglitazone in master formulation without considering the salt factor and revision of manufacturing outline as per innovator product. • Furthermore, firm shall submit fee of Rs. 7,500 for correction/pre-approval change in Form-5 (correction/pre-approval change in master formulation & manufacturing method), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
	Evaluation by PEC	• The firm have adjusted the weight of pioglitazone in master formulation after considering the salt factor and submitted revised manufacturing outline along with submission of Rs. 7500/- on deposit slip #36322906059.
	Decision: Approved. Firm shall submit the fee of Rs. 22,500/- for correction/pre-approval change in composition (correction/change of salt factor and adjustment of weight in master formulation), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	

Registration applications of locally manufactured New License / New Section on form 5F.

Firm has submitted copy of Acknowledgment of receipt of application for grant of additional section under DML No. 000465 (Formulations) to M/s Well Care Pharmaceuticals (Pvt.) Ltd., dated 24-11-2021 from Secretary Central Licensing Board. The letter specifies that CLB in its 283rd meeting held on 28-10-2021 has approved the grant of following additional section to M/s Well Care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha: 1. Capsule (General) New.		
410.	Name, address of Applicant / Marketing Authorization Holder	M/s Well care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Well care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12631: dated 24-03-2022.
	Details of fee submitted	PKR 30,000/-: dated 21/02/2022.
	The proposed proprietary name / brand name	Tzole 20mg Capsule.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Omeprazole (as enteric coated pellets) …….. 20mg
	Pharmaceutical form of applied drug	Oral capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	14's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Omeprazole 20mg delayed release capsule, USFDA Approved.
	For generic drugs (me-too status)	Helezol 20mg Capsule, Focus & Rulz, Reg. No. 027104.
	GMP status of the Finished product manufacturer	Not submitted.
	Evidence of section approval.	Capsule (general) - New section approved vide No.F.1-12/97-Lic (Vol-II) dated 24-11-2021.
	Name and address of API manufacturer.	Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification

		of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months. Batches: (OEC-8.5-001, OEC-8.5-002 & OEC-8.5-003)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for quality tests (Description, identification, Average weight, dissolution & assay) for their product against Omega 20mg Capsule. Firm has submitted CDP against the same brand i.e. Omega 20mg Capsule manufactured by the Ferozesons. However, no strength, Batch number, manufacturing date, Expiry date etc. are mentioned.
	Analytical method validation/verification of product	Not submitted.

STABILITY STUDY DATA	
Manufacturer of API	Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore.
API Lot No.	OEC-08-040.
Description of Pack (Container closure system)	14 capsules are packed in Alu-Alu plain in packing box.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.		T1/21	T2/21	T3/21
Batch Size		4100 capsules	4100 capsules	4100 capsules
Manufacturing Date		10-2021	10-2021	10-2021
Date of Initiation		15-10-2021	15-10-2021	15-10-2021
No. of Batches		03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No.43/2022-DRAP (AD-00196339815-153) dated 07-04-2022 on the basis of inspection conducted on 30-03-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No. 0571 dated 01-10-2021 of pharma zone chemical (Pvt.) Limited with buyer's name of Well care pharmaceuticals mentioning 1kg quantity of each 8.5% Omeprazole pellets & 22.5% pellets of Omeprazole.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section number	Observation	Submission by the firm.
1.	1.3.4	• Valid copy of DML of the manufacturer shall be submitted. • GMP certificate/last inspection report of the drug product manufacturer shall be submitted.	Copy of DML is submitted which is not in readable form. One page of inspection report is submitted conducted on 10-09-2021 signed by only one member out the three panel members wherein following is recommended; "Panel recommended resumption of production and grant of new capsule section. Detailed report was prepared on prescribed format and copy was handed over to the firm for record and reference."
2.	2.3	Table for literature references of the drug substance has mentioned drug substance in different pharmacopoeias. Clarification shall be submitted.	Firm has submitted that omeprazole pellets specification is manufacturer specifications and pharmacopoeial specifications were typographical error. ***No revised table for literature references has been submitted by the firm.***
3.	3.2.S.1.3	General properties, solubilities and physical form related data for the drug substance shall be submitted.	Submitted.
4.	3.2.S.4.1	• Finished product manufacturer has submitted Specification as per USP	Firm has submitted that omeprazole pellets specification is manufacturer specifications

		for drug substance while there is no monograph for the pellets in the USP.	and pharmacopoeial specifications were typographical error. ***No revised specifications are provided/submitted by the firm.***
5.	3.2.S.4.2	Analytical procedures submitted by the drug product manufacturer are completely different from drug substance manufacturer. Clarification is required.	Firm has submitted that drug substance analytical procedure is manufacturer specifications because Omeprazole EC pellets is not available in any pharmacopoeia. ***However, new* analytical procedure *for the drug substance as per manufacturer specifications are not provided by the drug product manufacturer.***
6.	3.2.S.4.3	Verification studies of the drug substance performed by the finished product manufacturer shall be submitted.	Submitted.
7.	.2.S.4.5.	Justification of specifications has declared USP specification. Clarification is required.	Firm has submitted that omeprazole pellets specification is manufacturer specifications and pharmacopoeial specifications were typographical error.
8.	3.2.S.5	COA of the reference standard used shall be submitted.	Firm has submitted COA for the working standard for omeprazole. ***However, the drug substance source as per submitted dossier is M/s Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore while the submitted COA is for M/s Vision Pharmaceuticals, Islamabad.***
9.	3.2.P.2	• Justification shall be submitted regarding dissolution and assay of the applied formulation in the pharmaceutical equivalence studies. As the medium of the dissolution and time are not in accordance with the monograph. • Justification shall be submitted for not performing CDP against the innovator product. • Justify the condition of dissolution used in comparative dissolution studies. • Justification shall be submitted for carrying dissolution studies up to 30 minutes time point only in 0.1N HCl in Comparative Dissolution studies.	Firm has submitted that test is performed according to the monograph but this time is typographical mistake. Firm has submitted new CDP results of the applied formulation with Risek 20mg capsules in three mediums and the f2 values are in acceptable range. ***However, submitted results are for Tzole 40mg capsule instead of 20mg & at acidic medium pH 1.2, results for only 45 minutes time points are submitted instead of 2 hours. Furthermore, pH of the medium is not mentioned with the submitted results.*** Firm has submitted that dissolution studies are performed according to monograph; we have 5 sampling intervals in 0.1 N HCl and phosphate buffer pH 4.5 and phosphate buffer pH 6.5. Firm has submitted that it is a typographic error while the dissolution in 0.1 N HCl is performing 120minutes. ***Initially submitted results have shown more than 10% release in 30 minutes while actually there should be NMT 10% in initial 2 hours.*** ***No details of the comparator product are submitted.***

		• No data for the comparator product for CDP has been submitted.	
10.	3.2.P.3.2	Justification shall be submitted for use of Omeprazole powder in the master formulation.	Firm has submitted that they have used Omeprazole 8.5% Ec pellets in the formulation. Omeprazole powder was typographical error.
11.	3.2.P.5.1	• Specification provided for the drug product has not mentioned dissolution at acidic stage. • Dissolution test shall be specified whether test I or any of the other test is followed by the drug product manufacturer or otherwise.	***No reply/justification is submitted against this point.*** ***No reply/justification is submitted against this point.***
12.	3.2.P.5.2	Analytical procedures for the drug product are completely different from the official monograph. Clarification is required.	Firm has submitted that all stability studies performed according to USP monograph. ***However, the conditions for dissolution test and conditions for assay test applied by the drug product manufacturer are completely different from that of the USP monograph. Standard solution, test soltion, wavelength applied & injection volume etc. all are different from USP.***
13.	3.2.P.5.2	Analytical method validation/verification of product shall be submitted.	Submitted.
14.	3.2.P.5.4	• Specification of dissolution test in the batch analysis are without time for buffer stage and without percentage for acid stage. • Batch analysis has only buffer stage dissolution results.	Firm has submitted that all limits are mentioned in analytical procedures but mistakenly not mentioned in batch analysis. ***No reply submitted against this point.***
15.	3.2.P.8.1	• Stability summary and conclusion has manufacturing date of Jan-2022 with batch No. of RLE-001, RLE-002 & RLE-003 while the stability data sheets have mentioned manufacturing date of 10-2021 with batch No. of T1/21, T2/21 & T3/21. Clarification is required.	Firm has submitted that manufacturing date of their batches is October, 2021 but the January 2021 is testing interval date.
16.	3.2.P.8.3	• Stability data sheets have no dissolution at acidic stage. Clarification is required. • Justification shall be submitted regarding the run time, injection volume and wavelength used for the assay of finished product as the applied run time, injection volume and wavelength are different from that of the official monograph.	Firm has submitted that details of dissolution at acidic and buffer stage are described in stability summary data sheets. ***Stability summary sheets have only buffer stage dissolution results dissolution stage results are missing in stability summary data sheets.*** Firm has submitted that testing of the product is performed as per USP. The run time is about 10 minutes and injection volume are 20µl and flow rate is 1ml/min. column used is 4.6 mm x 15cm; 5µm packing L1 and detector is 302nm. ***However, in the submitted chromatograms the conditions are different from that mentioned in the official pharmacopoeia. Official monograph has mentioned wavelength of 305nm while firm has applied 302nm.***

		• Stability data sheets have mentioned weight of capsule as 295 while the raw data has mentioned 235mg. Clarification is required. • Dates in the submitted chromatograms have been over written by hand. Clarification shall be submitted.	Firm has submitted that stability raw data sheets have two different weights one is content weight of pellets and second weight is gross weight with capsule shell. ***No reply submitted against this point.***
17.	3.2.P.8.3	Justification shall be submitted regarding the retention time of the omeprazole in the provided chromatograms as two different retention time are mentioned for the same omeprazole.	Firm has submitted that during stability studies they have used two different companies HPLC column in which one of that have minimum 5000 number of theoretical plates and other have less than 5000 plates due to which retention time have some difference. ***Submitted chromatograph have shown two different retention times for the omeprazole i.e. 5minutes and 10 minutes.***
18.		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Complete Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). • Provide specifications of HPLC system with its model including information whether gradient or isocratic column, 21 CFR compliance system. • Raw data sheets for dissolution and assay test of the finished product shall be submitted with calculation formula used. • Justification shall be submitted for the stability of both drug substance and finished product that the values at both accelerated and real time are exactly similar at same time points.	Only one-page Esomeprazole capsule 06 standard injection is provided. ***Not complete.*** Submitted. Only specifications of HPLC are provided while 21 CFR compliant certificate is not provided. Raw data sheets for dissolution and assay tests are not provided by the firm. Firm has submitted that they have performed only drug product stability studies accelerated and real time in different intervals but we take print out at same time after completion of stability studies. ***Real time and accelerated stability studies of both the drug substance and drug product of all three batches have exact similar values.***
19.		• Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance purchased and total quantity used in manufacturing and testing of all the three trial batches of Tzole 20mg capsule.	Firm has submitted that they purchased Omeprazole 8.5% and 22% each 1kg for three trial batches. Total material use in trial batches for testing. ***Executed BMR's have shown that in Tzole 20 mg capsules 8.5% of pellets have been used. Stability data sheets have three different batches each with 4100 capsules batch size.*** ***In this regard total number of capsules manufactured are;*** ***5600 x 3 = 12,300*** ***Each 20mg capsule will have 235mg of Omeprazole EC pellets.*** ***12300 x 235 = 2,890,500 mg of pellets*** ***2.89 kg pellets are required to fill the three trial batches while firm has purchased only 1kg.***

Decision: Registration Board decided to deferr the case for onsite verification and authenticity of the submitted stability data due to following observtaions:

- **Drug substance analytical procedure applied by the drug product manufacturer is different from that applied by the drug substance manufacturer.**
- **Submitted COA of working standard is from M/s Vision Pharmaceuticals whereas drug substance has been procured from M/s Pharmazone Chemicals.**
- **Submitted analytical record of CDP reflects that for pH 1.2, comparative dissolution studies have been conducted for 45 minutes only while the limits are NMT 10% release in pH 1.2 for two hours.**
- **The analytical method for dissolution test and for assay test applied by the drug product manufacturer are completely different in terms of run time, injection volume, wavelength, standard solution preparation etc.., from that of the USP monograph as also evident from the submitted HPLC chromatograms.**
- **Submitted HPLC chromatograms reflect two different retention time for 20mg and 40 mg Omeprazole EC pellets. i.e. 5minutes and 10 minutes.**
- **Quantity of Omeprazole pellets procured, as evident from submitted invoice is not justified for the manufacturing of trial batches of submitted batch size.**
- **Both accelerated and real time stability data sheets are having exactly similar values at same time points.**
- **Drug product Batch analysis has only buffer stage dissolution results.**
- **Stability data sheets have mentioned weight of capsule as 295 while the raw data has mentioned 235mg. Clarification is required.**
- **Dates in the submitted chromatograms have been over written by hand.**
- **Raw data sheets for dissolution and assay tests are not provided by the firm.**
- **Stability data sheets have mentioned weight of capsule as 295 while the raw data has mentioned 235mg.**

411.	Name, address of Applicant / Marketing Authorization Holder	M/s Well care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Well care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12659: dated 24-05-2022.
	Details of fee submitted	PKR 30,000/-: dated 21/02/2022.
	The proposed proprietary name / brand name	Rezole 40mg Capsule.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Omeprazole (as enteric coated pellets) …….. 40mg
	Pharmaceutical form of applied drug	Oral capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	14’s.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Omeprazole 40mg delayed release capsule, USFDA Approved.

	For generic drugs (me-too status)	Omega 40mg Capsule, Ferozsons Laboratories, Reg. No. 050818.
	GMP status of the Finished product manufacturer	Not submitted.
	Evidence of section approval.	Capsule (general) - New section approved vide No.F.1-12/97-Lic (Vol-II) dated 24-11-2021.
	Name and address of API manufacturer.	Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months. Batches: (OEC-22-001, OEC-22-002 & OEC-22-003)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for quality tests (Description, identification, Average weight, dissolution & assay) for their product against Omega 40mg Capsule. Firm has submitted CDP against the brand i.e. Risek 40mg Capsule manufactured by the Getz pharma. Results of the f2 values are in acceptable range.
	Analytical method validation/verification of product	Not submitted.
STABILITY STUDY DATA		

Manufacturer of API	Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore.		
API Lot No.	OEC-22-015.		
Description of Pack (Container closure system)	2 blisters of 7's capsules of Alu-Alu in single unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RLE001	RLE002	RLE001
Batch Size	5600 capsules	5600 capsules	5600 capsules
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	29-10-2021	29-10-2021	29-10-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No.43/2022-DRAP (AD-00196339815-153) dated 07-04-2022 on the basis of inspection conducted on 30-03-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No. 0571 dated 01-10-2021 of pharma zone chemical (Pvt.) Limited with buyer's name of Well care pharmaceuticals mentioning 1kg quantity of each 8.5% Omeprazole pellets & 22.5% pellets of Omeprazole.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section number	Observation	Submission by the firm.
1.	1.3.4	• Valid copy of DML of the manufacturer shall be submitted. • GMP certificate/last inspection report of the drug product manufacturer shall be submitted.	Copy of DML is submitted which is not in readable form. One page of inspection report is submitted conducted on 10-09-2021 signed by only one member out the three panel members wherein following is recommended; "Panel recommended resumption of production and grant of new capsule section. Detailed report was prepared on prescribed

			format and copy was handed over to the firm for record and reference."
2.	2.3	Table for literature references of the drug substance has mentioned drug substance in different pharmacopoeias. Clarification shall be submitted.	Firm has submitted that omeprazole pellets specification is manufacturer specifications and pharmacopoeial specifications were typographical error. ***No revised table for literature references has been submitted by the firm.***
3.	3.2.S.1.3	General properties, solubilities and physical form related data for the drug substance shall be submitted.	Submitted.
4.	3.2.S.4.1	• Finished product manufacturer has submitted Specification as per USP for drug substance while there is no monograph for the omeprazole pellets in the USP.	Firm has submitted that omeprazole pellets specification is manufacturer specifications and pharmacopoeial specifications were typographical error. ***No revised specifications are provided/submitted by the firm.***
5.	3.2.S.4.2	Analytical procedures submitted by the drug product manufacturer are different from drug substance manufacturer. Clarification is required.	Firm has submitted that drug substance analytical procedure is manufacturer specifications because Omeprazole EC pellets is not available in any pharmacopoeia. ***However, new* analytical procedure *for the drug substance as per manufacturer specifications are not provided by the drug product manufacturer.***
6.	3.2.S.4.3	Verification studies of the drug substance performed by the finished product manufacturer shall be submitted.	Submitted.
7.	.2.S.4.5.	Justification of specifications has declared USP specification. Clarification is required.	Firm has submitted that omeprazole pellets specification is manufacturer specifications and pharmacopoeial specifications were typographical error.
8.	3.2.S.5	COA of the reference standard used shall be submitted.	Firm has submitted COA for the working standard for omeprazole. ***However, the drug substance source as per submitted dossier is M/s Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore while the submitted COA is for M/s Vision Pharmaceuticals, Islamabad.***
9.	3.2.P.2	• Pharmaceutical equivalence studies are performed with Risek 40mg by Getz pharma while the results are given for Omega 40mg by Ferozsons laboratories. Clarification is required. • Justification shall be submitted for not performing CDP against the innovator product. • Justification shall be submitted regarding dissolution and assay of the applied formulation in the pharmaceutical equivalence studies. As the medium of the dissolution and time are not in accordance with the monograph.	Firm has submitted that it was typographic error and pharmaceutical equivalence studies are performed with Risek. ***No reply submitted.*** Firm has submitted that test is performed according to the monograph but this time is typographical mistake. Firm has submitted that dissolution studies are performed according to monograph; we have 5 sampling intervals in 0.1 N HCl and

		• Justify the condition of dissolution used in comparative dissolution studies. • Justification shall be submitted for carrying dissolution studies up to 30 minutes time point only in 0.1N HCl in Comparative Dissolution studies.	phosphate buffer pH 4.5 and phosphate buffer pH 6.5. Firm has submitted that it is a typographic error while the dissolution in 0.1 N HCl is performing 120minutes.
10.	3.2.P.5.2	• Analytical procedures for the drug product are different from the official monograph. Clarification is required. • Assay in the official monograph is through HPLC while applicant has mentioned UV spectroscopy in its analytical procedures. Clarification shall be submitted.	***No reply/justification submitted.*** ***No reply/justification submitted.***
11.	3.2.P.5.2	Analytical method validation/verification of product shall be submitted.	
12.	3.2.P.5.4	• Specification of dissolution test in the batch analysis are without time for buffer stage and without percentage for acid stage. • Batch analysis has only buffer stage dissolution results.	***No reply/justification submitted.*** ***No reply/justification submitted.***
13.	3.2.P.8.3	• Stability data sheets have no dissolution at acidic stage. Clarification is required. • Weight/10 capsule in the stability data sheets is 268mg ± 10%. Clarification shall be submitted in this regard. • Raw data sheets for stability has mentioned label claim of 20mg. clarification shall be submitted. • Justification shall be submitted regarding the run time for the assay of finished product as the applied run time is different from that of the official monograph. • Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance purchased and total quantity used in manufacturing and testing of all the three trial batches of Rezole 40mg capsule.	***No reply/justification submitted.*** ***No reply/justification submitted.*** ***No reply/justification submitted.*** ***No reply/justification submitted.*** ***No reply/justification submitted.***
14.	3.2.P.8.3	Justification shall be submitted regarding the retention time of the omeprazole in the provided chromatograms as two different retention time are mentioned for the same omeprazole.	***No reply/justification submitted.***
15.		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	***No reply/justification submitted.*** ***No reply/justification submitted.***

		• Complete Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). • Provide specifications of HPLC system with its model including information whether gradient or isocratic column, 21 CFR compliance system. • Raw data sheets for dissolution and assay test of the finished product shall be submitted with calculation formula used. • Justification shall be submitted for the stability of both drug substance and finished product that the values at both accelerated and real time are exactly similar at same time points.	***No reply/justification submitted.*** ***No reply/justification submitted.*** ***No reply/justification submitted.***

Decision: Registration Board decided to deferr the case for onsite verification and authenticity of the submitted stability data due to following observtaions:

- **Drug substance analytical procedure applied by the drug product manufacturer is different from that applied by the drug substance manufacturer.**
- **Submitted COA of working standard is from M/s Vision Pharmaceuticals whereas drug substance has been procured from M/s Pharmazone Chemicals.**
- **Submitted analytical record of CDP reflects that for pH 1.2, comparative dissolution studies have been conducted for 45 minutes only while the limits are NMT 10% release in pH 1.2 for two hours.**
- **Assay in the official monograph is through HPLC while applicant has mentioned UV spectroscopy in its analytical procedures.**
- **The analytical method for dissolution test and for assay test applied by the drug product manufacturer are completely different in terms of run time, injection volume, wavelength, standard solution preparation etc.., from that of the USP monograph as also evident from the submitted HPLC chromatograms.**
- **Submitted HPLC chromatograms reflect two different retention time for 20mg and 40 mg Omeprazole capsule.**
- **Quantity of Omeprazole pellets procured, as evident from submitted invoice is not justified for the manufacturing of trial batches of submitted batch size.**
- **Drug product Batch analysis has only buffer stage dissolution results.**
- **Dates in the submitted chromatograms have been over written by hand.**
- **Raw data sheets for dissolution and assay tests are not provided by the firm.**
- **Stability data sheets have no dissolution at acidic stage. Clarification is required.**
- **Raw data sheets for stability has mentioned label claim of 20mg.**
- **In performance of Assay test the applied run time is different from that of the official monograph.**

412.	Name, address of Applicant / Marketing Authorization Holder	M/s Well care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Well care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19735: dated 06-07-2022.
	Details of fee submitted	PKR 30,000/-: dated 31/05/2022.
	The proposed proprietary name / brand name	ESOWELL 20mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeprazole magnesium trihydrate enteric coated pellets Eq. to Esomeprazole …….. 20mg
	Pharmaceutical form of applied drug	Blue & Transparent colored Delayed Release Capsules
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitors).
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 40mg & 40mg delayed release capsule, USFDA Approved.
	For generic drugs (me-too status)	Nexum 20mg Capsule, Getz Pharma, Reg. No. 033890.
	GMP status of the Finished product manufacturer	Not submitted.
	Evidence of section approval.	Capsule (general) - New section approved vide No.F.1-12/97-Lic (Vol-II) dated 24-11-2021.
	Name and address of API manufacturer.	Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months. Batches: (EEC-22-002, EEC-22-003 & EEC-22-004)

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for quality tests (Description, identification, Weight variation, Loss on drying, Uniformity of dosage unit, dissolution & assay) for their product against Nexum 20mg capsules manufactured by Getz Pharma. Firm has submitted CDP against the same brand i.e. Nexum 20mg capsules (B. No. 384C12) manufactured by Getz Pharma.
	Analytical method validation/verification of product	Not submitted.

STABILITY STUDY DATA

Manufacturer of API	Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore.		
API Lot No.	EEC-22-222.		
Description of Pack (Container closure system)	14 capsules are blistered in Alu-Alu foil and with aluminum foil.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EW1	EW2	EW3
Batch Size	5600 capsules	5600 capsules	5600 capsules
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	16-10-2021	21-10-2021	23-10-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No.43/2022-DRAP (AD-00196339815-153) dated 07-04-2022 on the basis of inspection conducted on 30-03-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No. 0571 dated 01-10-2021 of pharma zone chemical (Pvt.) Limited with buyer's name of Well care pharmaceuticals mentioning 1kg quantity of each

		8.5% Omeprazole pellets & 22.5% pellets of Esomeprazole.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section number	Observation	Submission by the firm.
1.	1.3.4	• Valid copy of DML of the manufacturer shall be submitted. • GMP certificate/last inspection report of the drug product manufacturer shall be submitted.	Copy of DML is submitted which is not in readable form. One page of inspection report is submitted conducted on 10-09-2021 signed by only one member out the three panel members wherein following is recommended; "Panel recommended resumption of production and grant of new capsule section. Detailed report was prepared on prescribed format and copy was handed over to the firm for record and reference."
2.	1.5.15 – 1.5.19	All the commitments submitted are unsigned. Signed commitments shall be submitted.	Signed commitments are submitted by the firm.
3.	2.3	Table for literature references of the drug substance has mentioned drug substance in different pharmacopoeias. Clarification shall be submitted.	Firm has submitted that esomeprazole pellets specification is manufacturer specifications and pharmacopoeial specifications were typographical error. ***No revised table for literature references has been submitted by the firm.***
4.	3.2.S.4.1	Finished product manufacturer has submitted Specification as per USP for drug substance while there is no monograph for the pellets in the USP. Clarification is required.	Firm has submitted that it was typographical error while the specifications of the Esomeprazole pellets are manufacturer specifications. ***However, new specifications for the drug substance as per manufacturer specifications are not provided by the drug product manufacturer.***
5.	3.2.S.4.2	• Analytical procedure for drug substance provided by the finished product manufacturer is completely different from that of drug substance manufacturer. Clarification shall be submitted. • Drug substance has mentioned assay by HPLC while finished product manufacturer has mentioned UV spectroscopy. Clarification shall be submitted. • Justify the preparation of standard solution and sample solution in dissolution test of analytical	Firm has submitted that drug substance analytical procedure is manufacturer specifications. ***However, new* analytical procedure *for the drug substance as per manufacturer specifications are not provided by the drug product manufacturer.*** Firm has submitted that manufacturer have two testing methods one that on HPLC & other on UV and we have used HPLC method of testing for the drug substance testing. Firm has submitted that manufacturer has used omeprazole working standard against Esomeprazole test in assay and dissolution but

		procedure with respect to the drug substance manufacturer.	we have used esomeprazole working standard for the testing of Esomeprazole EC pellets. ***Completly different from manufacturer of drug substance.***
6.	3.2.S.4.3	Verification studies of the drug substance performed by the finished product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.5.	Justification of specifications for the drug substance shall be submitted.	Submitted.
8.	3.2.S.5	COA of the reference standard used shall be submitted.	Submitted.
9.	3.2.P.2	• Standard Operating procedure for product design and development is for syrup and suspension dosage form. • Justification shall be submitted for not performing CDP against the innovator product. • Justify the condition of dissolution used in comparative dissolution studies. • Justify the analytical procedure for CDP as it has mentioned Phosphate buffer of pH7.3, pH 11. • Justify the results of CDP at acid stage as more than 10% of the drug is released in 30 minutes.	***No reply submitted.*** Firm has submitted new CDP results of the applied formulation with Nexum 20mg capsules in three mediums and the f2 values are in acceptable range. ***However, at acidic medium pH 1.2, results for only 45 minutes time points are submitted instead of 2 hours.*** ***Furthermore, submitted CDP results for Esowell 20mg capsules are having 100% similar results and values as that of submitted results for Esocare 40mg.*** ***No justification is submitted against this point. pH 7.3 and pH 11 are used in the method.*** ***No justification is submitted against this point.*** ***No justification is submitted against this point.***
10.	3.2.P.5.1	• Specification provided for the drug product has not mentioned dissolution at acidic stage. • Dissolution test shall be specified whether test I or any of the other test is followed by the drug product manufacturer or otherwise.	Firm has submitted that details of dissolution at acidic and buffer stage are described in stability summary data sheets. ***Stability summary sheets have only buffer stage dissolution results dissolution stage results are missing in stability summary data sheets.*** ***No justification is submitted against this point.***
11.	3.2.P.5.2	• Calculation formula for assay test of the finished product is different from USP. Clarification is required. • Standard solution in dissolution test is different from USP. Clarification is required.	***No justification is submitted against this point.*** The manufacturer is using Omeprazole working standard against Esomeprazole test in assay and dissolution but we have used Esomeprazole working standard for the testing of Esomeprazole EC pellets. ***Official monograph has mentioned Omeprazole RS for preparation of standard***

			solution in the assay of Esomeprazole delayed release capsule.
12.	3.2.P.5.2	Analytical method validation/verification of product shall be submitted.	Submitted.
13.	3.2.P.5.4	• Specification of dissolution test in the batch analysis are without time for buffer stage and without percentage for acid stage. • Batch analysis has only buffer stage dissolution results.	Firm has submitted that all limits are mentioned in analytical procedures but mistakenly not mentioned in batch analysis. Firm has submitted that details of dissolution at acidic and buffer stage are described in stability summary data sheets. ***Stability summary sheets have only buffer stage dissolution results dissolution stage results are missing in stability summary data sheets.***
14.	3.2.P.8.3	• Stability data sheets have no dissolution at acidic stage. Clarification is required. • Stability raw data sheets provided for EW1 & EW2 have two different weight for the sample. Clarification shall be submitted. • Justification shall be submitted regarding the run time and injection volume used for the assay of finished product as the applied conditions are different from that of the official monograph.	Firm has submitted that details of dissolution at acidic and buffer stage are described in stability summary data sheets. ***Stability summary sheets have only buffer stage dissolution results dissolution stage results are missing in stability summary data sheets.*** Firm has submitted that stability raw data sheets of EC1 & EC2 have two different weights one is content weight of pellets and second weight is gross weight with capsule shell. Firm has submitted that testing of the product is performed as per USP. The run time is about 10 minutes and injection volume are 20µl and flow rate is 1ml/min. column used is 4.6 mm x 15cm; 5µmpacking L1 and detector is 302nm. ***Conditions are different from official monograph.***
15.		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Complete Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). • Provide specifications of HPLC system with its model including information whether gradient or isocratic column, 21 CFR compliance system. • Raw data sheets for dissolution and assay test of the finished product shall be submitted with calculation formula used. • Justification shall be submitted for the stability of finished product that the values at both accelerated and real time are exactly similar at same time points.	Only one-page Esomeprazole capsule 06 standard injection is provided. ***Not complete.*** Submitted. Only specifications of HPLC are provided while 21 CFR compliant certificate is not provided. ***Raw data sheets for dissolution and assay tests are not provided by the firm.*** ***No reply is submitted against this point.***

16.		Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance purchased and total quantity used in manufacturing and testing of all the three trial batches of Esowell 20mg capsule.	Firm has submitted that they purchased Esomeprazole 8.5% and 22% each 1kg for three trial batches. Total material use in trial batches for testing. ***However, firm has not provided any document for purchase of 8.5% Esomeprazole EC pellets.*** ***Executed BMR's have shown that in Esowell 20 mg capsules 22.5% of pellets have been used. Stability data sheets have three different batches each with 5600 capsules batch size.*** ***In this regard total number of capsules manufactured are;*** ***5600 x 3 = 16800*** ***Each 20mg capsule will have 88.8 mg of Esomeprazole EC pellets.*** ***16800 x 88.8 = 1,491,840 mg of pellets*** ***1.49 kg pellets are required to fill the three trial batches while firm has purchased only 1kg.***
17.		Justification shall be submitted regarding the chromatograms provided for Esowell 20mg and Esocare 40 mg capsules as chromatograms for both the products have same time and exact values in respect of everything.	Firm has submitted that the chromatograph of Esowell 20mg and Esocare 40mg are print on same date but the test is performed in different dates. ***Chromatographs of both the 20mg and 40mg Esomeprazole are complete copies in respect of time, Areas of the sample and standards, retentions time etc.***

Decision: Registration Board decided to defer the case for onsite verification and authenticity of the submitted stability data due to following observtaions:

- **Drug substance analytical procedure applied by the drug product manufacturer is different from that applied by the drug substance manufacturer.**
- **Submitted analytical record of CDP reflects that for pH 1.2, comparative dissolution studies have been conducted for 45 minutes only while the limits are NMT 10% release in pH 1.2 for two hours.**
- **The results of CDP at acid stage of different samples were more than 10% of the drug is released in 30 minutes.**
- **Firm has used Esomeprazole reference standard while Official monograph has mentioned Omeprazole RS for preparation of standard solution in the dissolution test of Esomeprazole delayed release capsule.**
- **Firm has used Esomeprazole reference standard while Official monograph has mentioned Omeprazole RS for preparation of standard solution in the assay test of Esomeprazole delayed release capsule.**
- **Verification of chromatographic conditions used in the dissolution and assay test of the Esomeprazole delayed release capsule from chromatograms in the HPLC software with reference to official monograph.**
- **Quantity of Esomeprazole pellets procured, as evident from submitted invoice is not justified for the manufacturing of trial batches of submitted batch size.**
- **Both accelerated and real time stability data sheets are having exactly similar values at same time points.**
- **The chromatograms for both Esomeprazole 20mg and 40mg capsules have same time and exact values in respect of everything.**

413.	Name, address of Applicant / Marketing Authorization Holder	M/s Well care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Well care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19734: dated 06-07-2022.
	Details of fee submitted	PKR 30,000/-: dated 31/05/2022.
	The proposed proprietary name / brand name	Esocare 40mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeprazole magnesium trihydrate enteric coated pellets Eq. to Esomeprazole …….. 40mg
	Pharmaceutical form of applied drug	Delayed Release Capsules.
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitors).
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 40mg & 40mg delayed release capsule, USFDA Approved.
	For generic drugs (me-too status)	Nexum 20mg Capsule, Getz Pharma, Reg. No. 033891.
	GMP status of the Finished product manufacturer	Not submitted.
	Evidence of section approval.	Capsule (general) - New section approved vide No.F.1-12/97-Lic (Vol-II) dated 24-11-2021.
	Name and address of API manufacturer.	Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data

		is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months. Batches: (EEC-22-002, EEC-22-003 & EEC-22-004)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for quality tests (Description, identification, Weight variation, Loss on drying, Uniformity of dosage unit, dissolution & assay) for their product against Nexum 20mg capsules manufactured by Getz Pharma. Firm has submitted CDP against the same brand i.e. Nexum 40mg capsules (B. No. 382C12) manufactured by Getz Pharma.
	Analytical method validation/verification of product	Not submitted.

STABILITY STUDY DATA

Manufacturer of API	Pharmazone Chemicals (Pvt.) Ltd., Plot No. 37, Sundar Industrial Estate, Lahore.		
API Lot No.	EEC-22-222.		
Description of Pack (Container closure system)	14 capsules are blistered in Alu-Alu foil and with aluminum foil.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EC1	EC2	EC3
Batch Size	5600 capsules	5600 capsules	5600 capsules
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	15-10-2021	20-10-2021	22-10-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No.43/2022-DRAP (AD-00196339815-153) dated 07-04-2022 on the basis of inspection conducted on 30-03-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No. 0571 dated 28-12-2021 of pharma zone chemical (Pvt.) Limited with buyer's name of Well care pharmaceuticals mentioning 1kg quantity of each 8.5% Omeprazole pellets & 22.5% pellets of Esomeprazole.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section number	Observation	Submission by the firm.
1.	1.3.4	• Valid copy of DML of the manufacturer shall be submitted. • GMP certificate/last inspection report of the drug product manufacturer shall be submitted.	Copy of DML is submitted which is not in readable form. One page of inspection report is submitted conducted on 10-09-2021 signed by only one member out the three panel members wherein following is recommended; "Panel recommended resumption of production and grant of new capsule section. Detailed report was prepared on prescribed format and copy was handed over to the firm for record and reference."
2.	1.5.15 – 1.5.19	All the commitments submitted are unsigned. Signed commitments shall be submitted.	Signed commitments are submitted by the firm.
3.	2.3	Table for literature references of the drug substance has mentioned drug substance in different pharmacopoeias. Clarification shall be submitted.	Firm has submitted that esomeprazole pellets specification is manufacturer specifications and pharmacopoeial specifications were typographical error. ***No revised table for literature references has been submitted by the firm.***
4.	3.2.S.4.2	• Analytical procedures for drug substance provided by the finished product manufacturer is completely different from that of drug substance manufacturer. Clarification shall be submitted. • Justify the preparation of standard solution and sample solution in dissolution test of analytical procedure with respect to the drug substance manufacturer.	Firm has submitted that drug substance analytical procedure is manufacturer specifications (In-house method). ***However, new* analytical procedure *for the drug substance as per manufacturer specifications are not provided by the drug product manufacturer.*** Firm has submitted that manufacturer has used omeprazole working standard against Esomeprazole test in assay and dissolution but we have used esomeprazole working standard for the testing of Esomeprazole EC pellets. ***Completely different from manufacturer of drug substance.***
5.	3.2.S.4.3	Verification studies of the drug substance performed by the finished product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.5.	Justification of specifications for the drug substance shall be submitted.	Submitted.

7.	3.2.P.2	• Standard Operating procedure for product design and development is for syrup and suspension dosage form. • Justification shall be submitted for not performing CDP against the innovator product. • Justify the condition of dissolution used in comparative dissolution studies. • Justify the analytical procedure for CDP as it has mentioned Phosphate buffer of pH7.3, pH 11. • Justify the results of CDP at acid stage as more than 10% of the drug is released in 30 minutes.	***No reply submitted.*** Firm has submitted new CDP results of the applied formulation with Nexum 20mg capsules in three mediums and the f2 values are in acceptable range. ***However, at acidic medium pH 1.2, results for only 45 minutes time points are submitted instead of 2 hours.*** ***Furthermore, submitted CDP results for Esocare 40mg capsules are having 100% similar results and values as that of submitted results for Esowel 20mg.*** ***No justification is submitted against this point.*** ***No justification is submitted against this point.*** ***No justification is submitted against this point***
8.	3.2.P.5.1	• Specification provided for the drug product has not mentioned dissolution at acidic stage. • Dissolution test shall be specified whether test I or any of the other test is followed by the drug product manufacturer or otherwise.	Firm has submitted that details of dissolution at acidic and buffer stage are described in stability summary data sheets. ***Stability summary sheets have only buffer stage dissolution results dissolution stage results are missing in stability summary data sheets.*** ***No justification is submitted against this point.***
9.	3.2.P.5.2	• Calculation formula for assay test of the finished product is different from USP. Clarification is required. • Standard solution preparation in dissolution test is different from USP. Clarification is required.	***No justification is submitted against this point.*** The manufacturer is using Omeprazole working standard against Esomeprazole test in assay and dissolution but we have used Esomeprazole working standard for the testing of Esomeprazole EC pellets. ***Official monograph has mentioned Omeprazole RS for preparation of standard solution in the assay of Esomeprazole delayed release capsule.***
10.	3.2.P.5.2	Analytical method validation/verification of product shall be submitted.	Submitted.
11.	3.2.P.5.4	• Specification of dissolution test in the batch analysis are without time for buffer stage and without percentage for acid stage. • Batch analysis has only buffer stage dissolution results.	Firm has submitted that all limits are mentioned in analytical procedures but mistakenly not mentioned in batch analysis. Firm has submitted that details of dissolution at acidic and buffer stage are described in stability summary data sheets.

			Stability summary sheets have only buffer stage dissolution results dissolution stage results are missing in stability summary data sheets.
12.	3.2.P.8.1	Stability summary and conclusion has manufacturing date of Jan-2022 with batch No. of RLE-001, RLE-002 & RLE-003 while the stability data sheets have mentioned manufacturing date of 10-2021 with batch No. of T1/21, T2/21 & T3/21. Clarification is required.	Firm has submitted that manufacturing date of their batches is October, 2021 but the January, 2021 is a testing interval date.
13.	3.2.P.8.3	• Stability data sheets have no dissolution at acidic stage. Clarification is required. • Stability raw data sheets provided for EC1 & EC2 have two different weight for the sample. Clarification shall be submitted. • Justification shall be submitted regarding the run time and injection volume used for the assay of finished product as the applied conditions are different from that of the official monograph.	Firm has submitted that details of dissolution at acidic and buffer stage are described in stability summary data sheets. ***Stability summary sheets have only buffer stage dissolution results dissolution stage results are missing in stability summary data sheets.*** Firm has submitted that stability raw data sheets of EC1 & EC2 have two different weights one is content weight of pellets and second weight is gross weight with capsule shell. Firm has submitted that testing of the product is performed as per USP. The run time is about 10 minutes and injection volume are 20µl and flow rate is 1ml/min. column used is 4.6 mm x 15cm; 5µm packing L1 and detector is 302nm. ***Conditions are different from official monograph.***
14.		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Complete Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). • Provide specifications of HPLC system with its model including information whether gradient or isocratic column, 21 CFR compliance system. • Raw data sheets for dissolution and assay test of the finished product shall be submitted with calculation formula used.	Only one-page Esomeprazole capsule 06 standard injection is provided. ***Not complete.*** Submitted. Only specifications of HPLC are provided while 21 CFR compliant certificate is not provided. ***Raw data sheets for dissolution and assay tests are not provided by the firm.***
15.		Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance purchased and total quantity used in manufacturing and testing of all the three trial batches of Esocare 40mg capsule.	Firm has submitted that they purchased Esomeprazole 8.5% and 22% each 1kg for three trial batches. Total material use in trial batches for testing. ***However, firm has provided the documents for 22.5% esomeprazole only for 1kg quantity. Executed BMR's have shown that in Esocare 40 mg capsules 22.5% of pellets have been used. Stability data sheets have three different batches each with 5600 capsules batch size.***

			In this regard total number of capsules manufactured are; ***5600 x 3 = 16800*** ***Each 40mg capsule will have 177.7mg of Esomeprazole EC pellets.*** ***16800 x 177.7 = 2,985,360 mg of pellets*** ***2.9 kg pellets are required to fill the three trial batches while firm has purchased only 1kg.***
16.		Justification shall be submitted regarding the chromatograms provided for Esowell 20mg and Esocare 40 mg capsules as chromatograms for both the products have same time and exact values in respect of everything.	Firm has submitted that the chromatograph of Esowell 20mg and Esocare 40mg are print on same date but the test is performed in different dates. ***Chromatographs of both the 20mg and 40mg Esomeprazole are complete copies in respect of time, Areas of the sample and standards, retentions time etc.***

Decision: Registration Board decided to defer the case for onsite verification and authenticity of the submitted stability data due to following observtaions:

- **Drug substance analytical procedure applied by the drug product manufacturer is different from that applied by the drug substance manufacturer.**
- **Submitted analytical record of CDP reflects that for pH 1.2, comparative dissolution studies have been conducted for 45 minutes only while the limits are NMT 10% release in pH 1.2 for two hours.**
- **The results of CDP at acid stage of different samples were more than 10% of the drug is released in 30 minutes.**
- **Firm has used Esomeprazole reference standard while Official monograph has mentioned Omeprazole RS for preparation of standard solution in the dissolution test of Esomeprazole delayed release capsule.**
- **Firm has used Esomeprazole reference standard while Official monograph has mentioned Omeprazole RS for preparation of standard solution in the assay test of Esomeprazole delayed release capsule.**
- **Verification of chromatographic conditions used in the dissolution and assay test of the Esomeprazole delayed release capsule from chromatograms in the HPLC software with reference to official monograph.**
- **Quantity of Esomeprazole pellets procured, as evident from submitted invoice is not justified for the manufacturing of trial batches of submitted batch size.**
- **Both accelerated and real time stability data sheets are having exactly similar values at same time points.**

The chromatograms for both Esomeprazole 20mg and 40mg capsules have same time and exact values in respect of everything.

On the recommendations of panel of experts, the CLB in its 273rd meeting held on 15th January, 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following four sections:

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Sachet Section (General)
iv. Dry powder injection section (pre-lyophilized) vial

414.	Name, address of Applicant / Marketing Authorization Holder	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura, Sheikhupura.
	Name, address of Manufacturing site.	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13056: dated 28-05-2022.
	Details of fee submitted	PKR 30,000/-: dated 13/05/2022.
	The proposed proprietary name / brand name	Levosulpiride 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains Levosulpiride …….. 25mg
	Pharmaceutical form of applied drug	Tablet.
	Pharmacotherapeutic Group of (API)	Antipsychotic.
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levosulpiride 25mg tablet, AIFA ITALY Approved.
	For generic drugs (me-too status)	Syconor Tablet 25mg, Opal Laboratories, Reg. No. 096116.
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020. General Tablet, General Capsule, General Sachet and General dry powder injectable (pre-lyophilized) Vial.
	Evidence of section approval.	Tablet general section is approved vide letter No. F.1-1/2016/Lic. Dataed 24-02-2020.
	Name and address of API manufacturer.	Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Official monograph of Levosulpiride is not present in USP/BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.

		Batches:(ALC/LSP/180304, ALC/LSP/180305, ALC/LSP/180306).
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is LEVOPRAID 25 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., B. No. AQ2309Q by performing quality tests (description, Assay, Dissolution). CDP has been performed against the same brand that is LEVOPRAID 25 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India.		
API Lot No.	31L01Z2122-001.		
Description of Pack (Container closure system)	White colored round, biconvex, plain on the both sides core tablet, blistered in Alu-Alu.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-001
Batch Size	2000 Tablets.	2000 Tablets.	2000 Tablets.
Manufacturing Date	08-2021	09-2021	09-2021
Date of Initiation	02-09-2021	06-09-2021	11-09-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate No. S-GMP/20102297 in the name of Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India issued by the Food & Drug Control Administration Gandhinagar, Gujarat State, India valid till 21-10-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No. ALC/20210215 wherein quantity of 1.1kg of Levosulpiride for test/analysis is imported by the firm. The invoice is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	3.2.S.4.1	Specifications of the drug substance by the finished product manufacturer shall be submitted.	***Firm has submitted specification for drug product instead of Drug substance.***
2.	3.2.S.4.2	Analytical procedures for the dug substance by the finished product manufacturer shall be submitted.	Submitted. ***However, the assay method in the analytical procedure submitted by the drug product manufacturer is by UV method and HPLC method while the drug substance has mentioned potentiometric method for the assay of the drug substance.***
3.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.4	Analytical record for the drug substance shall be submitted.	Firm has submitted analytical record for the drug substance. Submitted analytical has shown hand written date of 16-08-2021 while the firm has also submitted new COA with release date of 16-08-2021. However, in the initially submitted dossier, COA with release date of 24-05-2021 was submitted. Furthermore, submitted chromatograms of the drug substance in the analytical record submitted by the firm has also shown processing date of 22-05-2021.
5.	3.2.S.4.5	Justification of specifications for the drug substance shall be submitted.	***Justifications of specification submitted by the firm has assay value of 98.5% - 101% while the drug substance manufacturer has assay limits of 99% - 101%.***
6.	3.2.P.2.2	• Justification shall be submitted for not carrying the CDP against the innovator's brand.	Firm has submitted that according to WHO technical report series, No. 902,2002, if the innovator product is not available in the local market you can use the market leader product. They further submitted that in their case Levopraid 25mg tablets manufactured by Pacific pharmaceuticals under the license from Ravizza pharmaceutici S.p.A. Milan, Italy is considered appropriate for pharmaceutical equivalence studies as this

		• Calculation of F2 for CDP shall be submitted.	product is currently widely used within our local market and repute of company and the product is also satisfactory. Firm has submitted complete calculations of F2 value for all the three mediums used in CDP.
7.	3.2.P.8	Documents for the procurement of API with approval from DRAP mentioning the batch number of the drug substance shall be submitted.	Firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021 attested by Assistant Director I&E, DRAP, Lahore dated 12-04-2021. ***However, the API lot used in the formulation development studies has batch number of 31L01Z2122-001.***

Decision: Registration Board decided to defer the case for verification or submission of the following points:

- **COA of the drug substance initially submitted was having release date of 24-05-2021 while the substance clearance (invoice) is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.**
- **Furthermore, submitted chromatograms of the drug substance in the analytical record submitted by the firm has also shown processing date of 22-05-2021. Justification shall be submitted.**
- **API lot used in the formulation development studies has batch number of 31L01Z2122-001, while firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021.**

415.	Name, address of Applicant / Marketing Authorization Holder	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura, Sheikhupura.
	Name, address of Manufacturing site.	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13057: dated 28-05-2022.
	Details of fee submitted	PKR 30,000/-: dated 13/05/2022.
	The proposed proprietary name / brand name	Levosulpiride 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains Levosulpiride …….. 50mg
	Pharmaceutical form of applied drug	Tablet.
	Pharmacotherapeutic Group of (API)	Antipsychotic.
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Levosulpiride 50mg tablet, AIFA ITALY Approved.
	For generic drugs (me-too status)	Levopraid 50mg tablets, Opal Laboratories, Reg. No. 019755.

	GMP status of the Finished product manufacturer	New license granted on 13/02/2020. General Tablet, General Capsule, General Sachet and General dry powder injectable (pre-lyophilized) Vial.
	Evidence of section approval.	Tablet general section is approved vide letter No. F.1-1/2016/Lic. Dataed 24-02-2020.
	Name and address of API manufacturer.	Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Official monograph of Levosulpiride is not present in USP/BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months. Batches:(ALC/LSP/180304, ALC/LSP/180305, ALC/LSP/180306).
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is LEVOPRAID 25 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., B. No. AP0909Q by performing quality tests (description, Assay, Dissolution). CDP has been performed against the same brand that is LEVOPRAID 50 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India.		
API Lot No.	31L01Z2122-001.		
Description of Pack (Container closure system)	White colored round, biconvex, plain on the both sides core tablet, blistered in Alu-Alu.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 Tablets.	2000 Tablets.	2000 Tablets.
Manufacturing Date	08-2021	09-2021	09-2021
Date of Initiation	02-09-2021	06-09-2021	11-09-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate No. S-GMP/20102297 in the name of Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India issued by the Food & Drug Control Administration Gandhinagar, Gujarat State, India valid till 21-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No. ALC/20210215 wherein quantity of 1.1kg of Levosulpiride for test/analysis is imported by the firm. The invoice is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	3.2.S.4.1	Specifications of the drug substance by the finished product manufacturer shall be submitted.	Firm has submitted specification for drug substance. ***However, the assay limits provided by the drug product manufacturer are 98.5% - 101% while that of the drug substance manufacturer are 99% - 101%.***

2.	3.2.S.4.2	Analytical procedures for the dug substance by the finished product manufacturer shall be submitted.	***Not Submitted.***
3.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.4	Analytical record for the drug substance shall be submitted.	Firm has submitted analytical record for the drug substance. Submitted analytical has shown hand written date of 16-08-2021 while the firm has also submitted new COA with release date of 16-08-2021.
5.	3.2.S.4.5	Justification of specifications for the drug substance shall be submitted.	***Not Submitted.***
6.	3.2.P.2.2	• Justification shall be submitted for not carrying the CDP against the innovator's brand. • Calculation of F2 for CDP shall be submitted.	Firm has submitted that according to WHO technical report series, No. 902,2002, if the innovator product is not available in the local market you can use the market leader product. They further submitted that in their case Levopraid 50mg tablets manufactured by Pacific pharmaceuticals under the license from Ravizza pharmaceutici S.p.A. Milan, Italy is considered appropriate for pharmaceutical equivalence studies as this product is currently widely used within our local market and repute of company and the product is also satisfactory. Firm has submitted complete calculations of F2 value for all the three mediums used in CDP.
7.	3.2.P.8	Documents for the procurement of API with approval from DRAP mentioning the batch number of the drug substance shall be submitted.	Firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021 attested by Assistant Director I&E, DRAP, Lahore dated 12-04-2021. ***However, the API lot used in the formulation development studies has batch number of 31L01Z2122-001.***

Decision: Registration Board decided to defer the case for verification or submission of the following points:

- **COA of the drug substance initially submitted was having release date of 24-05-2021 while the substance clearance (invoice) is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.**
- **Furthermore, submitted chromatograms of the drug substance in the analytical record submitted by the firm has also shown processing date of 22-05-2021. Justification shall be submitted.**
- **API lot used in the formulation development studies has batch number of 31L01Z2122-001, while firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021.**

Registration applications of locally manufactured (Human) drugs on Form 5F.

416.	Name, address of Applicant / Marketing Authorization Holder	M/s Tabros Pharma (Pvt.) Ltd., L-20/B, Sector-22, F.B. Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Tabros Pharma (Pvt.) Ltd., L-20/B, Sector-22, F.B. Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23870 dated 31-08-2021.
	Details of fee submitted	PKR 30,000/- dated 16-08-2021.
	The proposed proprietary name / brand name	Elzanor 5mg/850mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……5mg Metformin HCl ……850mg
	Pharmaceutical form of applied drug	Immediate release film coated tablets.
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. A10BD20.
	Reference to Finished product specifications	Tabros Specifications.
	Proposed Pack size	1×14's
	Proposed unit price	As per DPC.
	The status in reference regulatory authorities	Synjardy 5 mg/850 mg film-coated tablets, MHRA approved.
	For generic drugs (me-too status)	Diampa-M 5mg/850mg Tablet, Getz Pharma, Reg. No. 103093.
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted on 28-02-2020
	Evidence of section approval.	Tablet section vide letter No. F.2-5/87-Lic. (Vol-III) 30-06-2020.
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin City, Liaoning Province, China. GMP certificate issued by Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone valid till 23-08-2023. **Metformin HCl:** Aarti drugs Limited (Unit-II), Plot No. 211 & 213, Road No. 2 G.I.D.C., Sarigam City Dist. Valsad, Gujrat State, India. GMP certificate No. 20031933 issued by Food & Drugs Control Administration Gandhinagar, Gujrat State India valid till 19-03-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per template provided in 293 DRB meeting. Firm has submitted summarized information related to general information, nomenclature, structure, general properties, solubilities, physical description, manufacturer, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted data for facilities, equipments and regional information.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to general information, nomenclature, structure, general properties, solubilities, physical description, manufacturer, Characterization, impurities, Specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug Substance)	Stability study conditions: **Empagliflozin:** Real time: 30°C ± 2°C / 65%RH ± 5% RH for 24 months. Accelerated: 40°C ± 2°C / 75% RH ± 5 %RH for 6 months. Batches: (20160606, 20161017, 20161219) **Metformin HCl:** Real time: 30°C ± 2°C / 75% RH ± 5% RH for 24 months. Accelerated: 40°C ± 2°C / 75% RH ± 5 %RH for 6 months. Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	Firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator product Synjardy 5mg/850mg tablet, Batch No. 902007, Mfg. date Feb-19, Exp. Date Jan-22 manufactured by Boehringer Ingelheim Limited by performing quality tests (Appearance, Identification, disintegration time, water content, Assay & Dissolution). CDP has been performed against the same brand that is Synjardy 5mg/850mg tablet in Acid media (pH 1.2), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are in the acceptable range.
	Analytical method validation /verification of product	Analytical method validation for drug substance (Empagliflozin & Metformin HCl) performed by drug product manufacturer also submitted including following parameters: Linearity & Range, Accuracy, Precision, Specificity. Method validation studies for finished product have submitted including following parameters: Linearity & range, Accuracy, Precision, Specificity, Detection limit, Quantitation limit, Robustness, Stability indicating.
STABILITY STUDY DATA		
Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin City, Liaoning Province, China. **Metformin HCl:**	

	Aarti drugs Limited (Unit-II), Plot No. 211 & 213, Road No. 2 G.I.D.C., Sarigam City Dist. Valsad, Gujrat State, India.		
API Lot No.	Metformin HCl (MEF10020695). Empagliflozin (E-20190921-D02-E06-01)		
Description of Pack (Container closure system)	Alu-Alu foil packed in unit carton (1×14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 09months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	TR001-5/ELZN	TR002-5/ELZN	TR003-5/ELZN
Batch Size	1100 tablets	1100 tablets	1100 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	12-09-2020	12-09-2020	12-09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel: 1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board). 2. Dr. Saif-Ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted copy of GMP certificate for M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China issued by Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone The certificate is valid till 23-08-2023. **Metformin HCl:** The firm has submitted copy of GMP certificate No. 20031933 for M/s Aarti Drugs limited, India 20031933 issued by Food & Drugs Control Administration Gandhinagar, Gujrat State India The certificate is valid till 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has provided attested commercial invoice No. HN200424-L dated 21-05-2020 wherein they imported 0.4Kg Empagliflozin from M/s Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin City, Liaoning Province, China. ADC signed Form 6, & invoice is available. Form 3 and form 7 also available. **Metformin HCl:** Firm has provided attested commercial invoice No. EXP/3151/19-20 dated March 07, 2020 wherein they imported 1000Kg API Metformin HCl from M/s. Aarti drugs limited India. Form 3 and form 7 also available.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.6.5	Valid GMP certificate of drug substance manufacturer for Empagliflozin issued by the concerned regulatory authority shall be submitted.	The firm has submitted copy of GMP certificate for M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China issued by Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone The certificate is valid till 23-08-2023.
2.	3.2.S.2.2	Manufacturing process has not mentioned metformin HCl incorporation into the final product. Clarification is required.	Firm has submitted revised manufacturing process wherein they have incorporated the step of metformin HCl in the final product. *However, no fee is submitted by the firm for changes in the manufacturing outline.*
3.	3.2.S.4.2	Assay test of metformin HCl of the drug substance manufacturer is by potentiometry while the finished product manufacturer has applied HPLC method. Clarification is required.	Firm submitted that previously USP-42 described the potentiometric titration method for metformin HCl and the same method was used for analysis. Afterword's potentiometric method was switched to HPLC method, whereas HPLC method derived from the method present in JP (Metformin HCl Tablets) with slight modification. HPLC method is more reliable authenticated then potentiometry method. The HPLC assay method for drug substance validated as per ICH guidelines.
4.	3.2.S.4.4	Batch analysis of the drug substance (Metformin HCL) has mentioned in house specifications for the assay test. Clarification is required.	Assay of drug substance Metformin HCl is switched to potentiometric method to HPLC method. Hence in-house specification is mentioned.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

417.	Name, address of Applicant / Marketing Authorization Holder	M/s Tabros Pharma (Pvt.) Ltd., L-20/B, Sector-22, F.B. Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Tabros Pharma (Pvt.) Ltd., L-20/B, Sector-22, F.B. Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23871 dated 31-08-2021.
	Details of fee submitted	PKR 30,000/- dated 16-08-2021.
	The proposed proprietary name / brand name	Elzanor 12.5mg/850mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin …… 12.5mg Metformin HCl ……850mg
	Pharmaceutical form of applied drug	Immediate release film coated tablets.
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. A10BD20.
	Reference to Finished product specifications	Tabros Specifications.
	Proposed Pack size	1×14's
	Proposed unit price	As per DPC.
	The status in reference regulatory authorities	Synjardy 12.5 mg/850 mg film-coated tablets, MHRA approved.
	For generic drugs (me-too status)	Xenglu -Met 12.5/850mg Tablets, Hilton Pharma, Reg. No. 093103.
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted on 28-02-2020
	Evidence of section approval.	Tablet section vide letter No. F.2-5/87-Lic. (Vol-III) 30-06-2020.
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin City, Liaoning Province, China. GMP certificate issued by Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone valid till 23-08-2023. **Metformin HCl:** Aarti drugs Limited (Unit-II), Plot No. 211 & 213, Road No. 2 G.I.D.C., Sarigam City Dist. Valsad, Gujrat State, India. GMP certificate No. 20031933 issued by Food & Drugs Control Administration Gandhinagar, Gujrat State India valid till 19-03-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per template provided in 293 DRB meeting. Firm has submitted summarized information related to general information, nomenclature, structure, general properties, solubilities, physical description, manufacturer, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted data for facilities, equipments and regional information.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to general information, nomenclature, structure, general

		properties, solubilities, physical description, manufacturer, Characterization, impurities, Specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug Substance)	Stability study conditions: **Empagliflozin:** Real time: 30°C ± 2°C / 65%RH ± 5% RH for 24 months. Accelerated: 40°C ± 2°C / 75% RH ± 5 %RH for 6 months. Batches: (20160606, 20161017, 20161219) **Metformin HCl:** Real time: 30°C ± 2°C / 75% RH ± 5% RH for 24 months. Accelerated: 40°C ± 2°C / 75% RH ± 5 %RH for 6 months. Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	Firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator product Synjardy 12.5mg/850mg tablet, Batch No. 003442, Mfg. date Feb-19, Exp. Date Jan-22 manufactured by Boehringer Ingelheim Limited by performing quality tests (Appearance, Identification, disintegration time, water content, Assay & Dissolution). CDP has been performed against the same brand that is Synjardy 5mg/850mg tablet in Acid media (pH 1.2), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are in the acceptable range.
	Analytical method validation /verification of product	Analytical method validation for drug substance (Empagliflozin & Metformin HCl) performed by drug product manufacturer also submitted including following parameters: Linearity & Range, Accuracy, Precision, Specificity. Method validation studies for finished product have submitted including following parameters: Linearity & range, Accuracy, Precision, Specificity, Detection limit, Quantitation limit, Robustness, Stability indicating.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin City, Liaoning Province, China. **Metformin HCl:** Aarti drugs Limited (Unit-II), Plot No. 211 & 213, Road No. 2 G.I.D.C., Sarigam City Dist. Valsad, Gujrat State, India.
API Lot No.	Metformin HCl (MEF10020695). Empagliflozin (E-20190921-D02-E06-01)
Description of Pack (Container closure system)	Alu-Alu foil packed in unit carton (1×14's)

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 09months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	TR001-6/ELZN	TR002-6/ELZN	TR003-6/ELZN
Batch Size	1100 tablets	1100 tablets	1100 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	12-09-2020	12-09-2020	12-09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel: 1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board). 2. Dr. Saif-Ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted copy of GMP certificate for M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China issued by Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone The certificate is valid till 23-08-2023. **Metformin HCl:** The firm has submitted copy of GMP certificate No. 20031933 for M/s Aarti Drugs limited, India 20031933 issued by Food & Drugs Control Administration Gandhinagar, Gujrat State India The certificate is valid till 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has provided attested commercial invoice No. HN200424-L dated 21-05-2020 wherein they imported 0.4Kg Empagliflozin from M/s Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin City, Liaoning Province, China. ADC signed Form 6, & invoice is available. Form 3 and form 7 also available. **Metformin HCl:** Firm has provided attested commercial invoice No. EXP/3151/19-20 dated March 07, 2020 wherein they imported 1000Kg API Metformin HCl from M/s. Aarti drugs limited India. Form 3 and form 7 also available.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.6.5	Valid GMP certificate of drug substance manufacturer for Empagliflozin issued by the concerned regulatory authority shall be submitted.	The firm has submitted copy of GMP certificate for M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China issued by Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone The certificate is valid till 23-08-2023.
2.	3.2.S.2.2	Manufacturing process has not mentioned metformin HCl incorporation into the final product. Clarification is required.	Firm has submitted revised manufacturing process wherein they have incorporated the step of metformin HCl in the final product. *However, no fee is submitted by the firm for changes in the manufacturing outline.*
3.	3.2.S.4.2	Assay test of metformin HCl of the drug substance manufacturer is by potentiometry while the finished product manufacturer has applied HPLC method. Clarification is required.	Firm submitted that previously USP-42 described the potentiometric titration method for metformin HCl and the same method was used for analysis. Afterword's potentiometric method was switched to HPLC method, whereas HPLC method derived from the method present in JP (Metformin HCl Tablets) with slight modification. HPLC method is more reliable authenticated then potentiometry method. The HPLC assay method for drug substance validated as per ICH guidelines.
4.	3.2.S.4.4	Batch analysis of the drug substance (Metformin HCL) has mentioned in house specifications for the assay test. Clarification is required.	Assay of drug substance Metformin HCl is switched to potentiometric method to HPLC method. Hence in-house specification is mentioned.
5.	3.2.P.2.3	Manufacturing process development, specifications are for 5mg/850mg tablets. Clarification is required.	Firm submitted that it is typographic error and also provided correct document.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

418.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 22586 dated 17-08-2021.
	Details of fee submitted	PKR 30,000/-: dated 09-07-2021.
	The proposed proprietary name / brand name	Duvel Plus XR Tablet 50mg + 500mg.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin ……. 50mg Metformin HCl (as extended release) …….. 500mg
	Pharmaceutical form of applied drug	Film-coated Extended-release tablet
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Martin Dow specifications.
	Proposed Pack size	7's, 10's, 14's, 20's & 28's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	JANUMET® XR 50/500 (sitagliptin and metformin hydrochloride extended release) tablets, USFDA approved.
	For generic drugs (me-too status)	Inosita Plus XR Tab 50/500 Tablet, PharmEvo (Pvt) Ltd., Reg. No. 090993.
	GMP status of the Finished product manufacturer	GMP certificate issued 11-06-2020 on the basis of inspection conducted on 07-05-2019.
	Evidence of section approval.	Tablet (general) section approved vide letter No. F. 2-6/86-Lic (Vol-V) dated 30-07-2018.
	Name and address of API manufacturer.	**Sitagliptin phosphate monohydrate:** Lianyungang Jari Pharmaceutical Co., Ltd**.** No. 18, Zhenhua Road, Lianyungang, China. Validity 11-04-2024. **Metformin HCl:** IPCA Laboratories Limited. H-4, MIDC, WALUJ Aurangabad, Aurangabad 431136, Maharashtra State, India. Validity 27-08-2021.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of in APIMFs of both drug substances.
	Stability studies (Drug substance.)	Stability study conditions: **Sitagliptin Phosphate Monohydrate.** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches: (20160301, 20160302, 20160303) **Metformin HCl.** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004 ML2RMI)

	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator product that is Janumet XR tablet 50mg+500mg, batch No. S038857 by MSD international GmbH by performing quality tests (Identification, Weight variation, Assay, Dissolution, Impurities). CDP has been performed against the same brand that is Janumet XR tablet 50mg+500mg by MSD international GmbH in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Sitagliptin phosphate monohydrate:** Lianyungang Jari Pharmaceuticals Co., Ltd**.** No. 18, Zhenhua Road, Lianyungang City, Jiangsu province, China **Metformin HCl:** IPCA Laboratories Limited. H-4, MIDC, WALUJ Aurangabad, Aurangabad 431136, Maharashtra State, India.		
API Lot No.	Sitagliptin phosphate monohydrate; 2005000020 (20200401), 2008000002 (20200602), Metformin HCl: 1908000095 (19370ML2ARMI), 2011000079 (20212ML2ARMI).		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2x7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1392-L	NPD-T-1409-P	NPD-T-1410-P
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	12-03-2021	29-03-2021	29-03-2021
Date of Initiation	02-04-2021	02-04-2021	02-04-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Empator 10mg Tablets which was conducted on

		6th August 2019 and was presented in 291st meeting of Registration Board held on 02nd – 4th September 2019. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software. • The firm has audit trail reports available. The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** Copy of GMP certificate for Lianyungang Jari Pharmaceuticals Co., Ltd issued by Lianyungang Drug Administration & Valid up to 11-April-2024 is submitted. **Metformin HCl:** Copy of GMP Certificate for IPCA Laboratories Limited (Certificate: New-WHO-GMP/CERT/AD/67318/2018/11/24741) dated 31-08-2018 valid till 27-08-2021 issued by Food and Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai-400051 Maharashtra, India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin phosphate monohydrate** Firm has submitted commercial invoice No. 20YX2025B dated 16-07-2020 for Sitagliptin Phosphate Monohydrate B. No. 20200602 attested by the Assistant Director, DRAP, Karachi. Firm has also provided commercial invoice No. 20YX2015B dated 20-04-2020 for Sitagliptin Phosphate Monohydrate B. No. 20200401 attested by the Assistant Director, DRAP, Karachi. **Metformin HCl:** Firm has provided commercial invoice No. MEG1920/1631259 dated 03-07-2019 for metformin HCl B. No. 19370ML2ARMI attested by the Assistant Director, DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section number	Observation.	Response by the firm.
1.	**1.3.4**	Valid copy of DML of the applicant shall be submitted. Valid GMP certificate/inspection report conducted within last three years shall be submitted.	Firm has submitted valid copy of DML w.e.f. 09-02-2021. Firm has also submitted GMP inspection report 20-10-2021 wherein it is concluded that the firm is considered to be operating at good level of compliance with cGMP guidelines.
2.	**1.6.5**	Valid GMP certificate of the API manufacturer of metformin HCl, issued	Firm has submitted Copy of GMP Certificate for IPCA Laboratories Limited

		by the relevant regulatory authority shall be submitted.	(Certificate No.: New-WHO-GMP/CERT/AD/104179/2021/11/37725) dated 28-10-2021 valid till 27-10-2024 issued by Food and Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai-400051 Maharashtra, India.
3.	**2.3**	• Table for literature references for the drug substance i.e. Metformin HCl does not declare the status in Japanese pharmacopoeia. • The submitted BMR does not reflect performance of dissolution for Metformin HCl before proceeding for seal & active coating step. Justification shall be submitted for proceeding further without establishing the Dissolution profile of Metformin HCl.	• Firm has provided revised table for literature references for the drug substance i.e. Metformin HCl wherein they declare the status in Japanese pharmacopoeia. The dissolution testing was performed at final stage and results were well within specified limits. Since the trial were satisfactory at core stage, a decision was made on risk basis to perform the dissolution testing at final stage after multiple coating to better evaluate the impact on all stability batches. Satisfactory initial and stability results are also evident on Metformin HCl dissolution performance.
4.	**3.2.S.4.2**	• Analytical procedure submitted by the drug substance manufacturer for the Assay test of Metformin HCl is different from that adopted by the drug product manufacturer. Clarification is required. • USP monograph of Metformin HCl mentions use of 25-cm column in the Assay test, while the applicant has declared use of 250cm column for the same. Justification is required.	• Firm has submitted that Manufacturer has adopted the test method Assay by Titration based on USP old version that was official at the time of manufacturing **(Lot No. 20212 ML2ARMI/Mfg. Date: Feb.2020)** and also the assay limits were set accordingly. The API lot was tested at Martin Dow in December 2020 and method adopted Assay by HPLC along with revised limits according to updated versions of USP monograph (Official as of November 2020). • Firm has submitted that it is a typo error. The actual column used is 250 instead of 25.
5.	**3.2.S.4.4**	Assay limits for Metformin HCl provided by the drug product manufacturer is different from that declared by the drug substance manufacturer.	Firm has submitted that Manufacturer has adopted the test method Assay by Titration based on USP old version that was official at the time of manufacturing **(Lot No. 20212 ML2ARMI/Mfg. Date: Feb.2020)** and also the assay limits were set accordingly. The API lot was tested at Martin Dow in December 2020 and method adopted Assay by HPLC along with revised limits according to updated versions of USP monograph (Official as of November 2020).
6.	**3.2.P.8.3**	• ADC attested invoices from DRAP for metformin HCl B. No. 20212ML2ARMI used in stability studies and product development shall be submitted.	• Firm has provided commercial invoice dated 09-12-2020 mentioning Metformin HCl B. No. 20212ML2ARMI attested by Assistant Director I&E, DRAP, Karachi.

		• Date of manufacturing of B # NPD-T-1392-L is 12-03-2021 while the analysis date is 02-04-2021. Justification for this delay shall be submitted.	• Batch was manufactured on 12/03/2021 and was processed after each stage satisfactory testing result to finished product with final coat. The finished product was received by 17/03/2021 in the lab for final testing and after satisfactory test results of 02 other batches which was received in 31-03-2021, stability initiated along with the other two batches on 02/04/2021.
		• Submitted CDP results are for capsules formulation instead of tablets. Clarify.	• Firm has submitted that it was typo error.
7.		• Justification of 50% extra amount of Sitagliptin in master formulation (which is required to be based on study/scientific rationale) for which firm has stated that it was taken to compensate the loss during coating.	• The 50% excess quantity mentioned in the BPR is for the clarity of the reviewer and the document itself. Excess quantity was added in coating material i.e., Propyl gallate, Polyethylene Glycol 6000, Hydroxyprop.Methylcell.2910/6CP, Kaolin along with it is the **API Sitagliptin Phosphate Monohydrate** to compensate for the process loss faced while Coating operation is being carried out, as it is an API coated tablet. As it's a universal truth, losses are observed/experienced during coating and thus extra quantities are added as a recompense. These extra quantities do not become part of the final film coated product, as is evident in the **Assay** results of **Sitagliptin** which are well within limits as per label claim.
		• Actual quantity of water used for the preparation of Active coating solution does not equate to the 50% extra than that mentioned for each tablet.	• Firm has submitted that the actual water quantity mentioned in the PBR is a typographical error while the calculation is correct as of 50% excess quantity to match with rest of the formulation.
		• The submitted product development record does not reflect performance of Uniformity of dosage units' test by way of Assay for Sitagliptin before proceeding for final film coating step. Justification shall be submitted for proceeding further without establishing the content of Sitagliptin.	• The uniformity of content for sitagliptin was performed at final stage as per procedure and results were found well within specified limits. The assay (Sitagliptin) was performed on API coat stage before proceeding the next final stage of film coating while it was decided to perform the uniformity of dosage units (Sitagliptin) on finished stage on risk basis and later results were found satisfactory.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

	• **Regsitartion Board directed the firm to include performance of dissolution profile for commercial batches at in-process stage of Metformin HCl extended release core prior to proceeding for Active coating of other drug substance.**	
419.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21177 dated 03-08-2021.
	Details of fee submitted	PKR 30,000/-: dated 22-06-2021.
	The proposed proprietary name / brand name	Duvel Plus XR Tablet 100mg + 1000mg.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin …… 100mg Metformin HCl (as extended release) …….. 1000mg
	Pharmaceutical form of applied drug	Film-coated Extended-release tablet
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Martin Dow specifications.
	Proposed Pack size	7's, 10's, 14's, 20's & 28's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	JANUMET® XR 100/1000 (sitagliptin and metformin hydrochloride extended release) tablets, USFDA approved.
	For generic drugs (me-too status)	Inosita Plus XR Tab 100/1000 Tablet, PharmEvo (Pvt) Ltd., Reg. No. 090993.
	GMP status of the Finished product manufacturer	GMP certificate issued 11-06-2020 on the basis of inspection conducted on 07-05-2019.
	Evidence of section approval.	Tablet (general) section approved vide letter No. F. 2-6/86-Lic (Vol-V) dated 30-07-2018.
	Name and address of API manufacturer.	**Sitagliptin phosphate monohydrate:** Lianyungang Jari Pharmaceutical Co., Ltd**.** No. 18, Zhenhua Road, Lianyungang, China. Validity 11-04-2024. **Metformin HCl:** IPCA Laboratories Limited. H-4, MIDC, WALUJ Aurangabad, Aurangabad 431136, Maharashtra State, India. Validity 27-08-2021.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of in APIMFs of both drug substances.
	Stability studies (Drug substance.)	Stability study conditions: **Sitagliptin Phosphate Monohydrate.** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches: (20160301, 20160302, 20160303) **Metformin HCl.** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004 ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator product that is Janumet XR tablet 100mg+1000mg, batch No. S011090 by MSD international GmbH by performing quality tests (Identification, Weight variation, Assay, Dissolution, Impurities). CDP has been performed against the same brand that is Janumet XR tablet 100mg+1000mg by Martin Dow Limited in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are >50% in all three dissolution medias.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Sitagliptin phosphate monohydrate:** Lianyungang Jari Pharmaceuticals Co., Ltd**.** No. 18, Zhenhua Road, Lianyungang City, Jiangsu province, China **Metformin HCl:** IPCA Laboratories Limited. H-4, MIDC, WALUJ Aurangabad, Aurangabad 431136, Maharashtra State, India.
API Lot No.	Sitagliptin phosphate monohydrate; 2008000002 (20200602), Metformin HCl: 1908000095 (19370ML2ARMI).
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2x7's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1366-L	NPD-T-1378-P	NPD-T-1379-P
Batch Size	8000 tablets	8000 tablets	8000 tablets
Manufacturing Date	22-02-2021	09-03-2021	09-03-2021
Date of Initiation	16-03-2021	16-03-2021	16-03-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Empator 10mg Tablets which was conducted on 6th August 2019 and was presented in 291st meeting of Registration Board held on 02nd – 4th September 2019. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software. • The firm has audit trail reports available. The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** Copy of GMP certificate for Lianyungang Jari Pharmaceuticals Co., Ltd issued by Lianyungang Drug Administration & Valid up to 11-April-2024 is submitted. **Metformin HCl:** Copy of GMP Certificate for IPCA Laboratories Limited (Certificate: New-WHO-GMP/CERT/AD/67318/2018/11/24741) dated 31-08-2018 valid till 27-08-2021 issued by Food and Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai-400051 Maharashtra, India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin phosphate monohydrate** Firm has submitted commercial invoice No. 20YX2025B dated 16-07-2020 for Sitagliptin Phosphate Monohydrate B. No. 20200602 attested by the Assistant Director, DRAP, Karachi. **Metformin HCl:** Firm has provided commercial invoice No. MEG1920/1631259 dated 03-07-2019 for metformin HCl B. No. 19370ML2ARMI attested by the Assistant Director, DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section number	Observation.	Response by the firm.
1.	**1.3.4**	• Valid copy of DML of the applicant shall be submitted. • Valid GMP certificate/inspection report conducted within last three years shall be submitted.	• Firm has submitted valid copy of DML w.e.f. 09-02-2021. • Firm has also submitted GMP inspection report 20-10-2021 wherein it is concluded that the firm is considered to be operating at good level of compliance with cGMP guidelines.
2.	**1.6.5**	Valid GMP certificate of the API manufacturer of metformin HCl, issued by the relevant regulatory authority shall be submitted.	Firm has submitted Copy of GMP Certificate for IPCA Laboratories Limited (Certificate No.: New-WHO-GMP/CERT/AD/104179/2021/11/37725) dated 28-10-2021 valid till 27-10-2024 issued by Food and Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai-400051 Maharashtra, India.
3.	**2.3**	• Table for literature references for the drug substance i.e. Metformin HCl does not declare the status in Japanese pharmacopoeia. • The submitted BMR does not reflect performance of dissolution for Metformin HCl before proceeding for seal & active coating step. Justification shall be submitted for proceeding further without establishing the Dissolution profile of Metformin HCl.	• Firm has provided revised table for literature references for the drug substance i.e. Metformin HCl wherein they declare the status in Japanese pharmacopoeia. The dissolution testing was performed at final stage and results were well within specified limits. Since the trial were satisfactory at core stage, a decision was made on risk basis to perform the dissolution testing at final stage after multiple coating to better evaluate the impact on all stability batches. Satisfactory initial and stability results are also evident on Metformin HCl dissolution performance.
4.	**3.2.S.4.2**	• Analytical procedure submitted by the drug substance manufacturer for the Assay test of Metformin HCl is different from that adopted by the drug product manufacturer. Clarification is required. • USP monograph of Metformin HCl mentions use of 25-cm column in the Assay test, while the applicant has declared use of 250cm column for the same. Justification is required.	• Firm has submitted that Manufacturer has adopted the test method Assay by Titration based on USP old version that was official at the time of manufacturing **(Lot No. 20212 ML2ARMI/Mfg. Date: Feb.2020)** and also the assay limits were set accordingly. The API lot was tested at Martin Dow in December 2020 and method adopted Assay by HPLC along with revised limits according to updated versions of USP monograph (Official as of November 2020). • Firm has submitted that it is a typo error. The actual column used is 250 instead of 25.
5.	**3.2.S.4.4**	Assay limits for Metformin HCl provided by the drug product manufacturer is different from that declared by the drug substance manufacturer.	Firm has submitted that Manufacturer has adopted the test method Assay by Titration based on USP old version that was official at the time of manufacturing **(Lot No. 20212 ML2ARMI/Mfg. Date: Feb.2020)** and also the assay limits were set accordingly. The API lot was tested at Martin Dow in December 2020 and method adopted Assay by HPLC along with revised limits according

			to updated versions of USP monograph (Official as of November 2020).
6.	**3.2.P.8.3**	• Date of manufacturing of B # NPD-T-1366-L is 22-02-2021 while the analysis date is 16-03-2021. Justification for this delay shall be submitted.	• Batch was manufactured on 22/02/2021 and was processed after each stage satisfactory testing result to finished product with final coat. The finished product was received by 25/02/2021 in the lab for final testing and after satisfactory test results of 02 other batches which manufactured in march, 2021, stability initiated along with the other two batches on 16/03/2021.
		• Submitted CDP results are for capsules formulation instead of instead of tablets. Clarify.	• Firm has submitted that it was typo error.
7.		• Justification of 50% extra amount of Sitagliptin in master formulation (which is required to be based on study/scientific rationale) for which firm has stated that it was taken to compensate the loss during coating.	• The 50% excess quantity mentioned in the BPR is for the clarity of the reviewer and the document itself. Excess quantity was added in coating material i.e., Propyl gallate, Polyethylene Glycol 6000, Hydroxyprop.Methylcell.2910/6CP, Kaolin along with it is the **API Sitagliptin Phosphate Monohydrate** to compensate for the process loss faced while Coating operation is being carried out, as it is an API coated tablet. As it's a universal truth, losses are observed/experienced during coating and thus extra quantities are added as a recompense. These extra quantities do not become part of the final film coated product, as is evident in the **Assay** results of **Sitagliptin** which are well within limits as per label claim.
		• Actual quantity of water used for the preparation of Active coating solution does not equate to the 50% extra than that mentioned for each tablet.	• Firm has submitted that the actual water quantity mentioned in the PBR is a typographical error while the calculation is correct as of 50% excess quantity to match with rest of the formulation.
		• The submitted product development record does not reflect performance of Uniformity of dosage units test by way of Assay for Sitagliptin before proceeding for final film coating step. Justification shall be submitted for proceeding further without establishing the content of Sitagliptin.	• The uniformity of content for sitagliptin was performed at final stage as per procedure and results were found well within specified limits. The assay (Sitagliptin) was performed on API coat stage before proceeding the next final stage of film coating while it was decided to perform the uniformity of dosage units (Sitagliptin) on finished stage on risk basis and later results were found satisfactory.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

• **Regsitartion board directed the firm to include performance of dissolution profile for commercial batches at in-process stage of Metformin HCl extended release core prior to proceeding for Active coating of other drug substance.**		
420.	Name, address of Applicant / Marketing Authorization Holder	Werrick Pharmaceuticals, Plot No. 216-217, Sector I-10/3, Industrial Area, Islamabad.
	Name, address of Manufacturing site.	Werrick Pharmaceuticals, Plot No. 216-217, Sector I-10/3, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales.
	Dy. No. and date of submission	Form-5F Dy. No. 23827 dated 31-08-2021.
	Details of fee submitted	PKR 30,000/-: dated 11-08-2021.
	The proposed proprietary name / brand name	Wardy plus Tablets 5mg/500mg.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Empagliflozin ……..…. 5mg Metformin Hydrochloride …… 500mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. (A10BD20)
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	14's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Synjardy 50 mg/ 500 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Diampa M tablets 5/500mg, Getz Pharma, Reg. No. 105287.
	GMP status of the Finished product manufacturer	GMP certificate issued on basi of inspection concducted on 12-8-2022
	Evidence of section approval.	Tablet (general) section approved vide No. F. 1-41/92-Lic (Vol II) dated 19-01-2019.
	Name and address of API manufacturer.	**Metformin hydrochloride.** Abhilasha Pharma Pvt. Limited 1408, 1409, GID, EST. Anklishwar, 393002, Gujrat state India. GMP Certificate No: 19081546 valid up to 25/08/2022 issued by Food & Drugs Control Administration of Gujarat State, India. **Empagliflozin:** Kaifeng Pharmaceutical (Group) Company Limited. China Address: No.1, Yunan Street, Kaifeng, Henan Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Metformin HCl:** The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (impurity A & unspecified), specifications, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of drug substance **Empagliflozin:** The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: **Metformin HCl.** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (MET099/13, MET100/13 & MET101/13) **Empagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (180205, 180227 & 180325)
	Module-III (Drug Product):	The firm has submitted detail of description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the Brand Leader Synjardy Tablets 5/500mg Batch No. 707713A by Boehringer Ingelheim by performing quality tests (Identification, Disintegration time, Tablet hardness, Assay, and Dissolution). CDP has been performed against the same brand that is Synjardy Tablets 5/500mg by Boehringer Ingelheim in Phosphate Buffer (pH 6.8), Acetate Buffer (pH 4.5) & Acid media (0.1N HCl). The Pharmaceutical Equivalence profiles are similar.
	Analytical method validation/verification of product	Method validation studies have been submitted including: system suitability, accuracy, and precision.

STABILITY STUDY DATA			
Manufacturer of API	**Metformin hydrochloride.** Abhilasha Pharma Pvt. Limited 1408, 1409, GID, EST. Anklishwar, 393002, Gujrat state India. GMP Certificate No: 19081546 valid up to 25/08/2022 issued by Food & Drugs Control Administration of Gujarat State, India. **Empagliflozin:** Kaifeng Pharmaceutical (Group) Company Limited. China Address: No.1, Yunan Street, Kaifeng, Henan Province, China.		
API Lot No.	MET065/19 (Metformin HCl) HF180721 (Empagliflozin)		
Description of Pack (Container closure system)	Alu-Alu Blister Strip packed in card box of unit carton of 14's Tablets.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 18 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6, 9, 12,18 (Months)		
Batch No.	TRIAL# 01	TRIAL# 02	TRIAL# 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	28-10-2019	29-10-2019	30-10-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Xetine 10mg tablets which was conducted on 03-03-2020 and was presented in 294th meeting of Registration Board held on 09th April, 2020. Registration Board decided to approve registration of Xetine Tablets 10mg and Xetine Tablets 20mg with innovator's specification
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Metformin hydrochloride.** Abhilasha Pharma Pvt. Limited 1408, 1409, GID, EST. Anklishwar, 393002, Gujrat state India. GMP Certificate No: 19081546 valid up to 25/08/2022 issued by Food & Drugs Control Administration of Gujarat State, India. **Empagliflozin:** Kaifeng Pharmaceutical (Group) Company Limited. China. Address: No.1, Yunan Street, Kaifeng, Henan Province, China.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice of: **Empagliflozin:** Firm has submitted copy of clearance certificate for Empagliflozin B. No. HF180721 attested by Assistant Director I&E, DRAP, Islamabad. Firm has also submitted copy of commercial Invoice No: CIN20180726G02 dated Jul. 26, 2018, with 1kg quantity of Empagliflozin B.

		No. HF180721 attested by Assistant Director I&E, DRAP, Islamabad. **Metformin HCl:** Not submitted.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.2	Table content from module 1 to module 5.	Firm has submitted table of contents from Module 1 to 5.
2.	1.3	• Valid copy of DML of the applicant shall be submitted. • Latest GMP certificate/inspection report conducted within last three years of the finished product manufacturer shall be provided.	Firm has submitte dcopy of GMP certificate eissued on basis of inspection conducted on 12-8-2022.
3.	1.6.5	• Section 1.6.5 has mentioned different drug substance manufacturers while module has mentioned some other manufacturers for the drug substances. Clarification is required. • GMP certificate for Empagliflozin drug substance manufacturer shall be submitted.	Firm has corrected section 1.6.5 wherein they have mentioned Kaifeng Pharmaceutical (Group) Company Limited, No.1, Yunan Street, Kaifeng, Henan Province, China and Abhilasha Pharma Pvt. Limited 1408, 1409, GID, EST. Anklishwar, 393002, Gujrat state India as the name & address of the drug substance manufacturers. Firm has submitted copy of GMP certificate no. HA20190069 valid upto 28-9-2024 issued in the name of M/s Kaifeng Pharmaceutical group Co., Ltd, China by NMPA of China.
4.	2.3	Table for literature references for the drug substance i.e. Metformin HCl does not declare the status other than BP. Clarification shall be submitted.	Firm has submitted revised table for literature references for the drug substance i.e. Metformin HCl wherein they have added USP, Ph. Eur and Japanese pharmacopoeias in in the literature.
5.	3.2.P.2.2.1	Pharmaceutical equivalence has mentioned pack size of 3 x 10's. clarification is required.	Firm has submitted that their proposed packaging at the time of launch would be an Alu-Alu having pack sizes of 2 x 7's, 2 x 10's & 3 x 10's. that's why the pack size was mentioned as 3 x 10's in the pharmaceutical equivalence data.
6.	3.2.P.8.3.	ADC attested invoices of the drug substance Metformin HCl used during product development and stability studies shall be submitted.	Firm has submitted Export Invoice No. Exp 013/2019-20 dated 05-06-2019 mentioning Metformin HCl, B. No. MET065/19 with quantity of 300kg attested by Assistant Director I & E, DRAP, Islamabad dated 01-07-19.

Decision: Approved.

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
421.	Name, address of Applicant / Marketing Authorization Holder	Wilson's Pharmaceuticals, Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.
	Name, address of Manufacturing site.	Wilson's Pharmaceuticals, Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales.
	Dy. No. and date of submission	Form-5F Dy. No. 26709 dated 27-09-2021.
	Details of fee submitted	PKR 75,000/-: dated 20-09-2021.
	The proposed proprietary name / brand name	Coldenol Sinus Severe Caplets (day).
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Caplet contains; Paracetamol …… 325mg Phenylephrine HCl …… 5mg Guaifenesin …… 200mg
	Pharmaceutical form of applied drug	Oral tablet.
	Pharmacotherapeutic Group of (API)	Paracetamol, combinations excl. Psycholeptics. (N02BE51)
	Reference to Finished product specifications	Manufacturer specifications.
	Proposed Pack size	10's, 20's & 30's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Tylenol Sinus Severe (day), USFDA is provided by the firm. However, the same could not be found in USFDA data. Daily med has the same product as OTC product with the following disclaimer: *Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*
	For generic drugs (me-too status)	Could not be confirmed.
	GMP status of the Finished product manufacturer	Inspection report of 24-01-2018. Not valid.
	Evidence of section approval.	Tablet (general) section approved vide No. F. 1-19/92-Lic (P1) dated 27-07-2015.
	Name and address of API manufacturer.	<u>Paracetamol:</u> Saakh Pharma (Pvt.) Ltd., C-7/1, North Western Industrial Zone. Port Qasim, Karachi.

		Guaifenesin: Zhejiang Haizhou Pharmaceutical Co., Ltd., linhai Industrial Zone, Linhai Zhejiang China. Phenylephrine Hydrochloride. M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzhen China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol (USP/BP), Guaifenesin (USP) and Phenylephrine HCl (USP/BP) is present respectively. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests impurities B,C,D, Individual Impurity I & any unspecified for Paracetamol, Impurities A,B,C and D for Guaifenesin and Impurities A,C,D,E and unspecified impurity for Phenylephrine HCl, specifications, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of the following drug substances as per Zone IV-a for both accelerated as well as real time conditions: Paracetamol: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 12 months. (Batch No. 18GN60001, 18GN60002, and 18GN60003) Guaifenesin: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. (Batch No. 08GF04156, 08GF04157, and 08GF04158) Phenylephrine hydrochloride. Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. (Batch No. PEH-160404, PEH-160405, and PEH-160406)
	Module-III (Drug Product):	The firm has submitted detail of description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against Tylenol Sinus Severe Caplets DAY by performing quality tests (Assay, Dissolution, Disintegration Time test).

		CDP has been performed against the same product that is Tylenol Sinus Severe Caplets DAY, Lot No. 485556 made in Italy, distributed by M/s Johnson & Johnson Consumer Inc., Mc Neil Consumer Healthcare Division USA in 0.1 N HCl, Acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted including: system suitability, accuracy, and precision.

STABILITY STUDY DATA

Manufacturer of API	Paracetamol: Saakh Pharma (Pvt.) Ltd., C-7/1, North Western Industrial Zone. Port Qasim, Karachi. Guaifenesin: Zhejiang Haizhou Pharmaceutical Co., Ltd., Linhai Industrial Zone, Linhai Zhejiang China. Phenylephrine Hydrochloride. M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzhen China.		
API Lot No.	Paracetamol (Batch No.19GN60209, Batch No.19GN60213) Guaifenesin (Batch No.18GF03204) Phenylephrine HCl (Batch No.PEH-180101Y1)		
Description of Pack (Container closure system)	Alu-Alu blister packed in card box unit carton of 10's, 20's & 30's.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1500 caplets	1500 caplets	1500 caplets
Manufacturing Date	17-12-2019	23-12-2019	23-12-2019
Date of Initiation	01-01-2020	01-01-2020	01-01-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted Reference of previous approval of applications with stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificates of: Paracetamol: Copy of GMP certificate No. 83/2020-DRAP(K) of M/s Saakh Pharma (Pvt.) Ltd., C-7/1, North Western Industrial Zone. Port Qasim, Karachi issued by DRAP Karachi valid till 18/06/2022. Guaifenesin: Copy of GMP certificate No. ZJ20180122 of Zhejiang Haizhou Pharmaceutical Co., Ltd., Linhai Industrial Zone, Linhai city Zhejiang China issued by China food & Drug Administration valid until 09-25-2023.

		Phenylephrine Hydrochloride. Not provided.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• **Paracetamol** Copy of commercial invoice No. PRT/2019/0191 dated 18/03/2019 is submitted. Copy of commercial invoice No. PRT/2019/0197 dated 25/03/2019 is submitted. • **Guaifenesin** Copy of clearance certificate attested by AD (I&E) DRAP, Islamabad dated 16/07/2018 along with commercial invoice No.130128 dated 22/06/2018 with quantity of 0.75Kg is submitted. • **Phenylephrine HCl** Copy of clearance certificate attested by AD (I&E) DRAP, Islamabad dated 10/05/2018 along with commercial invoice No. SZ-1803039 dated 12/04/2018 with quantity of 308.25 Gram is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.3	Valid copy of DML and latest GMP certificate/inspection report conducted within last three years of the finished product manufacturer shall be provided.	Firm has not provided any renewal of DML. Firm has submitted GMP inspection report dated 24-01-2018. ***Provided GMP inspection report is not within last three years.***
2.	1.5.9	Evidence of approval of applied formulation in reference regulatory authorities as decided by the registration board shall be submitted as the provided reference could not be confirmed.	Tylenol Sinus Severe (day), USFDA is provided by the firm. However, the same could not be found in USFDA data. Daily med has the same product as OTC product with the following disclaimer: *Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*
3.	1.6.5	• Address of the API manufacturer for guaifenesin provided in section 1.6.5 is different from that of mentioned in GMP certificate. Clarification is required. • Valid GMP certificate of the drug substance manufacturer (phenylephrine HCL) issued by	• Firm has submitted that due to typographical error, the address of the drug substance manufacturer mentioned in section 1.6.5 was written wrong. *Firm has submitted a document "Announcement of the state drug administration on matters concerning the implementation of the Drug Administration*

		the concerned / relevant regulatory authority shall be submitted.	*Law of the People's Republic of China" wherein under the heading of drug GMP & GSP management requirements following is stated.* *'starting from December 1, 2019 the pharmaceutical GMP and GSP certifications will be cancelled, GMP and GSP certificates will no longer be accepted and pharmaceutical GMP and GSP certificates will no longer be issued. Where current regulation require on-site inspection, on-site inspection shall be continued after December 1, 2019 and the company shall be notified of the on-site inspection results. '*
4.	3.2.S.4.2	<u>Guaifenesin:</u> • Analytical method used for drug substance (guaifenesin) by the drug substance manufacturer shall be submitted. • Analytical method provided by the drug product manufacturer for drug substance (guaifenesin) has mentioned 40g/ml while the pharmacopoeia has mentioned 40mcg/ml in Identification test. Clarification is required. <u>Phenylephrine HCL:</u> • Analytical method used for drug substance (phenylephrine HCL) by drug substance manufacturer shall be submitted.	Submitted. Firm has submitted that due typographic error 40g/ml was written instead of 40mcg/ml. However, finished product manufacturer has followed USP method for drug substance. Submitted.
5.	3.2.S.4.3	Verification studies of all the three drug substances performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	Batch analysis of paracetamol from Wilson pharma has not mentioned whether USP specifications or BP. Clarification is required.	Firm has submitted COA's wherein it is mentioned that the samples complies with both USP and BP.
7.	3.2.S.7.3	Both real time and accelerated stability study data for phenylephrine HCl from drug substance manufacturer shall be submitted.	Firm has submitted real time and accelerated stability study data for Phenylephrine HCl.
8.	3.2.P.2.	Qualitative composition of the applied formulation is different from reference product. Clarification is required.	• Firm has submitted that they used PVP K30 instead of HPC as binder in their formulation as both the materials are safely used in pharmaceutical industry for granulation purpose can be used interchangeably because of their excellent binding profiles, as mentioned in the hand book of pharmaceutical excipients. • Triacetin is used as plasticizer in the formulation and is used in the film coating to add plasticity to the film. Our film coating yields excellent film without use of plasticizer, so we didn't add triacetin in the formulation.

			• Carnauba wax is used to polish the caplet which is not necessarily required in our formulation. • Sucralose is not added in the formulation as it is used as sweetener and our formulation is neither chewable nor dispersible.
9.	3.2.P.2.2.1	Average weight of 10 tablets in pharmaceutical equivalence is 776.7gm. clarification is required.	Firm submitted that due to typographic error average weight of 10 tablets was mentioned 776.7 gm rather than 7.767gm.
10.	3.2.P.3.2	Batch formula has mentioned innovator's specification for paracetamol. clarification is required.	Firm has submitted new batch formula wherein USP specification is mentioned against paracetamol.
11.		Clearance certificate for Guaifenesin provided by the firm has mentioned 750Gm (0.75 Kg) quantity. While the firm has manufactured three trial batches of 1500 tablets each. With this respect only 900gm is required for the manufacturing of the said three trial batches. Clarification is required.	Firm has submitted that drug substance B. No. 18GF03204, quantity 750Gm was used in the manufacturing of trial 01, 02 trial batches. While B. No. 18GF03204 750gm & B. No. 18GF09667, 03 Kg respectively were used in the manufacturing of trial 03. We had submitted the clearance certificate of one batch 18GF03204 at the time of registration application submission, whereas the clearance certificate of the second batch was unintentionally overlooked. They also submitted the clearance certificate of the second batch (B. No. 18GF09667). ***However, there is no record of the second batch in the submitted application nor any verification studies of the said batch.*** ***Stability data sheets in the initial dossier has also mentioned batch No. 18GF03204 for all the three trial batches.***
12.	2.3.R	Dispensing of active materials without potency adjustment for Guaifenesin and Phenylephrine HCl. Justification is required.	Firm has submitted that potency was not adjusted for trial manufacturing batches (pilot scale) due to small batch size (1500 caplets) the adjustment amount was very low and does not affect the quality, efficacy and safety of the drug product. It is pertinent to mention here, that the finished drug product release limit is 90% - 110%. They also undertake that they will adjust the potency of drug substance at commercial batch for said drug product.
13.			Firm has submitted fee of 7500/- vide slip No. 67888642 dated 23-05-2022.

Decision: Deferred for further deliberation regarding regulatory stataus of applied formulation in reference regulatory authorities adopted by Regsitration Board in its 275th meeting.

422.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals Pvt. Ltd., 14 Km Adyala Road Post office Dahgal, Rawalpindi.
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt. Ltd., 14 Km Adyala Road Post office Dahgal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25528 dated 14-09-2021.
	Details of fee submitted	PKR 30,000/-: dated 31-08-2021.
	The proposed proprietary name / brand name	Admit XR 50mg/500mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sitagliptin as Phosphate Monohydrate ……. 50mg Metformin HCl (as extended release) …….. 500mg
	Pharmaceutical form of applied drug	Oral tablet.
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	14's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	JANUMET® XR 50/500 (sitagliptin and metformin hydrochloride extended release) tablets, USFDA approved.
	For generic drugs (me-too status)	Inosita Plus XR Tab 50/500 Tablet, PharmEvo (Pvt) Ltd., Reg. No. 090993.
	GMP status of the Finished product manufacturer	GMP certificate issued 28-08-2020 on the basis of inspection conducted on 25-09-2019.
	Evidence of section approval.	Tablet (general) section approved vide letter No. F. 1-18/92-Lic (Vol-II) dated 30-10-2019.
	Name and address of API manufacturer.	**Sitagliptin phosphate monohydrate:** Changzhou Pharmaceutical Factory, No. 518, East Laodong Road, Changzhou city China. Validity 12-11-2023. **Metformin HCl:** Smruthi Organics Limited, A-27, MIDC Chincholi, Tal-Mohol Solapur, Maharashtra State of India. Validity 13-11-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of of both drug substances.
	Stability studies (Drug substance.)	Stability study conditions: **Sitagliptin Phosphate Monohydrate.** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches: (20160301, 20160302, 20160303) **Metformin HCl.** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months

		Batches: (DMFH-026/10, DMFH-027/10, DMFH-028/10)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator product that is Janumet XR 50/500mg tablet 50mg+500mg, Lot No. S022563 by Merck Sharp & Dohme USA by performing quality tests (Identification, Average weight of tablets, Impurities, Assay, Dissolution, total aerobic microbial count). CDP has been performed against the same brand that is Janumet XR 50/500mg tablet 50mg+500mg, Lot No. S022563 by Merck Sharp & Dohme USA in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Sitagliptin phosphate monohydrate:** Changzhou Pharmaceutical Factory, No. 518, East Laodong Road, Changzhou city China. Validity 12-11-2023. **Metformin HCl:** Smruthi Organics Limited, A-27, MIDC Chincholi, Tal-Mohol Solapur, Maharashtra State of India. Validity 13-11-2022.		
API Lot No.	Sitagliptin phosphate monohydrate; B#20200805 Metformin HCl: BMET-009/20		
Description of Pack (Container closure system)	Alu-Alu blister of 2 x 7's light blue color oblong biconvex, plain, film coated tablets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	3500 tablets	3500 tablets	3500 tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	10-04-2021	10-04-2021	10-04-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last inspection report for Emdagan 10mg & 20mg Tablets conducted on 06-01-2021, approved in 289th meeting of Registration Board. Following are details of few points; • The HPLC software is 21CFR Compliant. • Audit trail reports were available and physically checked by the inspection team. • Firm has adequate monitoring and controls for stability chambers. • Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin Phosphate monohydrate:** Copy of GMP certificate No. Js20180928 Changzhou Pharmaceutical Factory, No. 518, East Laodong Road, Changzhou city China issued by the Jiangsu Drug Administration china is provided. Validity 12-11-2023 **Metformin HCl:** Copy of GMP Certificate for Smruthi Organics Limited, A-27, MIDC Chincholi, Tal-Mohol Solapur, Maharashtra State of India (Certificate: New-WHO-GMP/CERT/PD/86368/2019/11/30111) dated 14-11-2019 valid till 13-11-2023 issued by Food and Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai-400051 Maharashtra, India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin phosphate monohydrate** Firm has submitted commercial invoice No. 20YX2043B dated 11-09-2020 for Sitagliptin Phosphate Monohydrate B. No. 20200805 with quantity of 28kg x 12 drums (300kg) attested by the Assistant Director, DRAP, Islamabad. **Metformin HCl:** Firm has provided invoice No. E-185 dated 27-02-2020 for metformin HCl B. No. BMET-009/20 with quantity of 2000 kg attested by the Assistant Director, DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section number	Observation.	Response by the firm.
1.	2.3	• The submitted BMR does not reflect performance of dissolution for Metformin HCl before proceeding for active coating step. Justification shall be submitted for proceeding	Firm has submitted that Metformin HCl dissolution was performed on lab scale trial (B. No. LS-001) and also submitted data of lab scale trial wherein they have performed dissolution for Metformin HCl before proceeding for active coating step.

		further without establishing the Dissolution profile of Metformin HCl. • Table for literature references for the drug substance i.e. Metformin HCl does not declare the status in Japanese pharmacopoeia. Also, volume/most recent editions are not mentioned in the table for literature references.	Firm has submitted new table for literature references wherein they have added the status of Metformin HCl in Japanese pharmacopoeia. Volume/most recent editions are also mentioned in the new table for literature references. No fee has been submitted.
2.	2.3.R.1	• Justify the dispensed quantity of Sitagliptin against the actual potency declared in the COA of API.	As 64.25mg sitagliptin phosphate monohydrate is equal to 50mg of sitagliptin as free base. sitagliptin phosphate monohydrate is used in 20% excess amount to compensate process loss and is applied via film coating process. i.e. 64.25mg + 20% (77.1mg/tablet) is dispensed to achieve 100% assay of sitagliptin phosphate monohydrate.
3.	3.2.S.4.1	• Submitted COA for Metformin HCl of the finished product manufacturer does not reflects any specification and Batch number. Clarification is required. • Loss on drying test for metformin HCl by the finished product manufacturer has mentioned limits of NMT 0.5% at 80C while BP has mentioned maximum of 0.5% at 105C. Temperature conditions are not in accordance with the pharmacopoeial monograph. Clarification is required. • For specifications of drug substance Metformin HCl innovator's specifications are mentioned while monograph is available in USP. Clarification is required. • Specifications of Metformin HCl has assay limits of 98.5% - 101.0% while USP has mentioned 98% - 102%. Clarify	Firm has submitted new COA for Metformin HCL with BP specifications. Firm has submitted that it was typographical error and submitted new COA for Metformin HCL with temperature conditions in accordance with the pharmacopoeial monograph. i.e. NMT 0.5% at 105C. Firm has submitted that it was typographical error and the drug substance manufacturer followed BP specifications. Firm has submitted that specifications of Metformin HCl are as per BP monograph where assay limits of 98.5% - 101.0%.
4.	3.2.S.4.4	• Provide results of analysis of relevant batch(es) of Sitagliptin phosphate monohydrate performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture. • Provide results of analysis of relevant batch(es) of Metformin HCl performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture.	Firm has submitted COA for Sitagliptin phosphate monohydrate along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture. Firm has submitted COA for Metformin HCl along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture.

5.	3.2.P.1	Justification of 20% extra amount of Sitagliptin in master formulation (which is required to be based on study/scientific rationale) for which firm has stated that it was taken to compensate the loss during coating.	Firm has submitted that in lab scale trial to optimize the application of sitagliptin phosphate monohydrate to obtain 100% of drug, 20% excess quantity was added to compensate the loss during active coating of sitagliptin. For this purpose, 30% excess drug solution is prepared i.e. (64.25mg + 30% excessive drug = 83.525mg/tablet. This solution was applied in different stages. Summary is given below; • At first stage with 100% sitagliptin solution the assay results were 83.49%. • At second stage with 110% sitagliptin solution the assay results were 92.94%. • At first stage with 120% sitagliptin solution the assay results were 102.39%.
6.	3.2.P.2.3	Innovator product has polymeric coating over the active coating while there is no such polymeric coating of the applied formulation, clarification is required.	Firm has submitted that ingredients of their formulation are qualitatively same with reference product. Active drug sitagliptin is coated with soluble polymer carried by film coating with Opadry.
7.	3.2.P.8	• Only 03-month stability data is submitted. Stability study data both real time and accelerated for six months shall be submitted. • Protocol has mentioned API lot number for Empagliflozin instead on sitagliptin. Clarify. • Reference of previous approval of applications with stability study data of the firm shall be submitted.	Firm has submitted 06 month stability data for all the trial batches for both real time and accelerated conditions. Firm has submitted that it was due to typographic error. They also submitted new/corrected protocol. Submitted.
8.	3.2.P.8.3	Raw data sheets for assay test & dissolution test of the finished product shall be submitted.	Firm has submitted raw data sheets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Regsitartion board directed the firm to include performance of dissolution profile for commercial batches at in-process stage of Metformin HCl extended release core prior to proceeding for Active coating of other drug substance.**
- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

423.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals Pvt. Ltd., 14 Km Adyala Road Post office Dahgal, Rawalpindi.
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt. Ltd., 14 Km Adyala Road Post office Dahgal, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26414 dated 23-09-2021.
	Details of fee submitted	PKR 30,000/-: dated 20-09-2021.
	The proposed proprietary name / brand name	Admit XR 100mg/1000mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sitagliptin as Phosphate Monohydrate ……. 100mg Metformin HCl (as extended release) ……..1000mg
	Pharmaceutical form of applied drug	Oral tablet.
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	14's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	JANUMET® XR 100/1000 (sitagliptin and metformin hydrochloride extended release) tablets, USFDA approved.
	For generic drugs (me-too status)	Inosita Plus XR Tab 100/1000 Tablet, PharmEvo (Pvt) Ltd., Reg. No. 090992.
	GMP status of the Finished product manufacturer	GMP certificate issued 28-08-2020 on the basis of inspection conducted on 25-09-2019.
	Evidence of section approval.	Tablet (general) section approved vide letter No. F. 1-18/92-Lic (Vol-II) dated 30-10-2019.
	Name and address of API manufacturer.	**Sitagliptin phosphate monohydrate:** Changzhou Pharmaceutical Factory, No. 518, East Laodong Road, Changzhou city China. Validity 12-11-2023. **Metformin HCl:** Smruthi Organics Limited, A-27, MIDC Chincholi, Tal-Mohol Solapur, Maharashtra State of India. Validity 13-11-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of of both drug substances.
	Stability studies (Drug substance.)	Stability study conditions: **Sitagliptin Phosphate Monohydrate.** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches: (20160301, 20160302, 20160303) **Metformin HCl.** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DMFH-026/10, DMFH-027/10, DMFH-028/10)

	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator product that is Janumet XR 100/1000mg tablet, Lot No. S028886 by Merck Sharp & Dohme USA by performing quality tests (Identification, Average weight of tablets, Impurities, Assay, Dissolution, total aerobic microbial count). CDP has been performed against the same brand that is Janumet XR 100/1000mg tablet, Lot No. S028886 by Merck Sharp & Dohme USA in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Sitagliptin phosphate monohydrate:** Changzhou Pharmaceutical Factory, No. 518, East Laodong Road, Changzhou city China. Validity 12-11-2023. **Metformin HCl:** Smruthi Organics Limited, A-27, MIDC Chincholi, Tal-Mohol Solapur, Maharashtra State of India. Validity 13-11-2022.		
API Lot No.	Sitagliptin phosphate monohydrate; B#20200805 Metformin HCl: BMET-009/20		
Description of Pack (Container closure system)	Alu-Alu blister of 2 x 7's light blue color oblong biconvex, plain, film coated tablets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	20-04-2021	25-04-2021	25-04-2021
No. of Batches	03		
REQUEST OF EXEMPTION FROM ON SITE INSPECTION			
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.			
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last inspection report for Emdagan 10mg & 20mg Tablets conducted on 06-01-2021, approved in 289th meeting of Registration Board. Following are details of few points; • The HPLC software is 21CFR Compliant. • Audit trail reports were available and physically checked by the inspection team. • Firm has adequate monitoring and controls for stability chambers. • Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin Phosphate monohydrate:** Copy of GMP certificate No. Js20180928 Changzhou Pharmaceutical Factory, No. 518, East Laodong Road, Changzhou city China issued by the Jiangsu Drug Administration china is provided. Validity 12-11-2023 **Metformin HCl:** Copy of GMP Certificate for Smruthi Organics Limited, A-27, MIDC Chincholi, Tal-Mohol Solapur, Maharashtra State of India (Certificate: New-WHO-GMP/CERT/PD/86368/2019/11/30111) dated 14-11-2019 valid till 13-11-2023 issued by Food and Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai-400051 Maharashtra, India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin phosphate monohydrate** Firm has submitted commercial invoice No. 20YX2043B dated 11-09-2020 for Sitagliptin Phosphate Monohydrate B. No. 20200805 with quantity of 28kg x 12 drums (300kg) attested by the Assistant Director, DRAP, Islamabad. **Metformin HCl:** Firm has provided invoice No. E-185 dated 27-02-2020 for metformin HCl B. No. BMET-009/20 with quantity of 2000 kg attested by the Assistant Director, DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section number	Observation.	Response by the firm.
1.	2.3	• The submitted BMR does not reflect performance of dissolution for Metformin HCl before proceeding for active coating step. Justification shall be submitted for proceeding further without establishing the	Firm has submitted that Metformin HCl dissolution was performed on lab scale trial (B. No. LS-001) and also submitted data of lab scale trial wherein they have performed dissolution for Metformin HCl before proceeding for active coating step.

		Dissolution profile of Metformin HCl. • Table for literature references for the drug substance i.e. Metformin HCl does not declare the status in Japanese pharmacopoeia. Also, volume/most recent editions are not mentioned in the table for literature references.	Firm has submitted new table for literature references wherein they have added the status of Metformin HCl in Japanese pharmacopoeia. Volume/most recent editions are also mentioned in the new table for literature references. ***No fee has been submitted.***
2.	2.3.R.1	• Justify the dispensed quantity of Sitagliptin against the actual potency declared in the COA of API.	As 128.5mg sitagliptin phosphate monohydrate is equal to 100mg of sitagliptin as free base. sitagliptin phosphate monohydrate is used in 20% excess amount to compensate process loss and is applied via film coating process. i.e. 128.5mg + 20% (154.2mg/tablet) is dispensed to achieve 100% assay of sitagliptin phosphate monohydrate.
3.	3.2.S.4.1	• Submitted COA for Metformin HCl of the finished product manufacturer does not reflects any specification and Batch number. Clarification is required. • Loss on drying test for metformin HCl by the finished product manufacturer has mentioned limits of NMT 0.5% at 80C while BP has mentioned maximum of 0.5% at 105C. Temperature conditions are not in accordance with the pharmacopoeial monograph. Clarification is required. • For specifications of drug substance Metformin HCl innovator's specifications are mentioned while monograph is available in USP. Clarification is required. • Specifications of Metformin HCl has assay limits of 98.5% - 101.0% while USP has mentioned 98% - 102%. Clarify	Firm has submitted new COA for Metformin HCL with BP specifications. Firm has submitted that it was typographical error and submitted new COA for Metformin HCL with temperature conditions in accordance with the pharmacopoeial monograph. i.e. NMT 0.5% at 105C. Firm has submitted that it was typographical error and the drug substance manufacturer followed BP specifications. Firm has submitted that specifications of Metformin HCl are as per BP monograph where assay limits of 98.5% - 101.0%.
4.	3.2.S.4.4	• Provide results of analysis of relevant batch(es) of Sitagliptin phosphate monohydrate performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture. • Provide results of analysis of relevant batch(es) of Metformin HCl performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture.	Firm has submitted COA for Sitagliptin phosphate monohydrate along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture. Firm has submitted COA for Metformin HCl along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture.

5.	3.2.P.1	Justification of 20% extra amount of Sitagliptin in master formulation (which is required to be based on study/scientific rationale) for which firm has stated that it was taken to compensate the loss during coating.	Firm has submitted that in lab scale trial to optimize the application of sitagliptin phosphate monohydrate to obtain 100% of drug, 20% excess quantity was added to compensate the loss during active coating of sitagliptin. For this purpose, 30% excess drug solution is prepared i.e. (128.5mg + 30% excessive drug = 167.05mg/tablet. This solution was applied in different stages. Summary is given below; • At first stage with 100% sitagliptin solution the assay results were 83.43%. • At second stage with 110% sitagliptin solution the assay results were 92.56%. At first stage with 120% sitagliptin solution the assay results were 101.01%.
6.	3.2.P.2.3	Innovator product has polymeric coating over the active coating while there is no such polymeric coating of the applied formulation, clarification is required	Firm has submitted that ingredients of their formulation are qualitatively same with reference product. Active drug sitagliptin is coated with soluble polymer carried by film coating with Opadry.
7.	3.2.P.8	• Only 03 months stability data is submitted. Stability study data both real time and accelerated for six months shall be submitted. • Reference of previous approval of applications with stability study data of the firm shall be submitted.	Firm has submitted 06 months stability data for all the trial batches for both real time and accelerated conditions. Submitted.
8.	3.2.P.8.3	Raw data sheets for assay test & dissolution test of the finished product shall be submitted.	Firm has submitted raw data sheets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Regsitartion board directed the firm to include performance of dissolution profile for commercial batches at in-process stage of Metformin HCl extended release core prior to proceeding for Active coating of other drug substance.**
- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

424.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23844: dated 31-08-2021.
	Details of fee submitted	PKR 30,000/-: dated 11/08/2021.
	The proposed proprietary name / brand name	Glucosta 100mg Tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Rebamipide ……..…100mg.
	Pharmaceutical form of applied drug	White color, round shaped Film coated tablets.
	Pharmacotherapeutic Group of (API)	Drugs for Peptic Ulcer and Gastro-Oesophageal Reflux Disease (GORD)
	Reference to Finished product specifications	JP Specifications.
	Proposed Pack size	20's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Rebamipide Tablets 100mg "Otsuka, PMDA Japan approved.
	For generic drugs (me-too status)	Mucosta 100mg tablets, Otsuka Pharmaceutical, Reg. No. 078129.
	GMP status of the Finished product manufacturer	GMP certificate issued on the basis of inspection conducted on 24-10-2018. Not valid.
	Evidence of section approval.	Tablet section (general) vide letter No. F. 1-1/96-Lic. (Vol-II) dated 13-06-2017.
	Name and address of API manufacturer.	M/s Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd., No. 1, Huanan Yi Road Changshou, Chongqing, China. Certificate No. CQ20190051 Issued by Chongqing Drug Administration. Valid till 11-04-2024.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Ticagrelor is based Inhouse Specification. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 10%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (Rp090801V, Rp090802V & Rp090803V)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Mucosta 100mg tablets of M/s Otsuka Pharmaceutical Co., Ltd., Japan., (Batch No: MC189182, Mfg. 09-2018 & Exp. 09-2021) by performing quality tests (Physical attributes, Identification, Assay & Dissolution). CDP has been performed against the same brand that is Mucosta 100mg tablets of M/s Otsuka Pharmaceutical Co., Ltd., Japan., (Batch No: MC189182, Mfg. 09-2018 & Exp. 09-2021) in in three different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer & pH 6.8 Phosphate buffer
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd., No. 1, Huanan Yi Road Changshou, Chongqing, China. Certificate No. CQ20190051 Issued by Chongqing Drug Administration. Valid till 11-04-2024.		
API Lot No.	Rp200501		
Description of Pack (Container closure system)	Alu-alu blister pack of 20's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	ST21B039	ST21B040	ST21B041
Batch Size	3000 tabs	3000 tabs	3000 tabs
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	30-03-2021	30-03-2021	30-03-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Promig plus tablets 375mg/20mg which was conducted on 1st, 13th & 14th March 2019 and was presented in 289th meeting of Registration Board held on 14-16th May, 2019. According to the report following points were confirmed.

		• The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. CQ20190051 of drug substance manufacturer issued by Chongqing Drug Administration, China valid till 11/04/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No. KSDS202008232 dated 11-09-2020 attested by the Assistant Director I&E, DRAP, Islamabad dated 01-10-2020. Details are also mentioned on the invoice with quantity of 05Kg with B. No. Rp200501.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section Number	Observations	Response of the firm.
1.	1.3.4	GMP certificate/inspection report conducted within last three years shall be submitted.	Firm has submitted GMP certificate No. F. 3-16/2018-Addl. Dir. (QA&LT)-1 dated 04-01-2022 on the basis of inspection conducted on 03-01-2022.
2.	1.6.5	This section has mentioned Dapagliflozin instead of Rebamipide. Also, section 2.3.S is for Dapagliflozin. Clarification is required.	Firm has submitted that it was due to typographic error and they now submitted corrected document with Rebamipide heading.
3.	3.2.S.4.2	• In analytical procedures for drug substance limits for loss on drying test, limits for chloride test, limits for residue on ignition test, upper limits in assay test are not provided by finished product manufacturer. Clarification is required. • Assay test of the drug substance provided by both the drug substance manufacturer and finished product manufacturer is different from that of the official monograph. Clarification is required. • In method verification protocol provided by the finished product manufacturer, the formula used for assay calculation has no weight of sample. Clarification is required.	Firm has provided revised SAP wherein they have added the limits for the mentioned tests. Firm has submitted that they have performed the assay test both on JP and manufacturer's specs. In JP specs assay is performed by titration while manufacturer used HPLC method for assay. We cross verified the titration result against HPLC method. But we missed to submit the titration result. They also provided the results of titrimetric assay. Firm submitted that due to typographical mistake weight of sample is missed in formula but in result they have consider the weight of sample. Also provided revised protocol.

4.	3.2.S.4.5	Inhouse specifications are mentioned for drug substance while the official monograph of the drug substance is available in JP. Clarify.	Firm has submitted that the specifications are as JP specs. They also provided justification of specifications.
5.	3.2.S.7.3	• Long term stability data of the drug substance has 65% ± 10% RH condition. Clarification is required. • Also, one batch long term condition is 60% ± 10% RH. Clarification is required. • Accelerated stability data sheets for drug substance is mentioned 98%-102% limits for the assay test while the monograph has mentioned 99% - 101%. Clarification is required.	Firm has submitted revised stability of the drug substance with 30°C ± 2°C / 65% ± 5%RH for real time and 40°C ± 2°C / 75% ± 5%RH for accelerated condition. New data sheets of the stability studies have the assay limit of 99% - 101%. ***Only the stability conditions and assay limits have been changed while the data remains the same as previous.***
6.	3.2.P.2	Comparative study protocol has mentioned assay limits of 90%-110% for finished drug product while the monograph has mentioned 95%-105%. Clarification is required.	Firm has submitted that this change in limit came across due to typographical mistake in comparative study protocol. They also provided revised document.
7.	3.2.P.2.3	Critical quality attributes are for soglumet tablets.	Firm has submitted that CQA's mentioned are correct for glucosta tablets. However, due to typographic error heading was for Soglumet tablets.
8.	3.2.P.5.1	This section has mentioned innovator's specifications. Clarification is required.	Firm has submitted that specifications of FPP are as per JP specs.
9.	3.2 P.5.2	• Sample preparation method for dissolution test shall be submitted. • Identify the Q value in dissolution limits. • Clarification regarding dilution factor used in sample preparation in dissolution test is required.	Submitted. The term Q is used to describe the cumulative percent of drug dissolved with respect to label claim at the selected time point of the dissolution test. A Q value of 80% is generally recommended, except when a justification with adequate data are provided to support a lower Q value (e.g., clinical or bioavailability/bioequivalence data). Q values above 80% are not generally used. In case of this product JP just provide the limit i-e NLT 75.0% after 60 minutes. Firm has submitted that it is second dilution of the sample to make the final concentration of sample solution as 22mcg/ml.
10.	3.2.P.8.2	Stability study protocol has mentioned assay limits of 90%-110% and dissolution limits of NLT 80% in 30minutes which are in contradiction to the official monograph. Clarification is required.	Firm has submitted that this change in limit came across due to typographical mistake in stability study protocol. They submitted revised document for the same.
11.	3.2.P.8.3	• Stability study data sheet has mentioned 30-03-2021 as date of initiation of stability study data while the data has shown initial testing on 10-03-2021. Clarify. • Only three-month stability data is submitted. Stability study data of six months shall be submitted.	Initial testing is start on 10-03-2022 and testing end on 11-03-2022. Gap between Initial testing and initiation stability occur due to non-availability of machine for blistering, so gap occur in Initial testing data and initiation stability data. Firm has submitted 06 months stability data for all the three batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

425.	Name, address of Applicant / Marketing Authorization Holder	M/s Novamed Pharmaceuticals (Pvt.) Ltd., 28km Ferozepur Road Lahore.
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt.) Ltd., 28km Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18480 dated 01-07-2021.
	Details of fee submitted	PKR 30,000/-: dated 07-06-2021.
	The proposed proprietary name / brand name	Dapaflo 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin …… 5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors.
	Reference to Finished product specifications	In-House
	Proposed Pack size	10’s, 14’s, 20’s 28’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA® 5mg (dapagliflozin) film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Xiga 5mg tablets, CCL Pharmaceuticals, Reg. No. 090504
	GMP status of the Finished product manufacturer	License granted on 08/04/2006 and renewed on 08/04/2021 General tablet section approved and GMP certificate on 31/08/2021.
	Evidence of section approval.	Tablet section as per GMP certificate.
	Name and address of API manufacturer.	Name: Jiangsu Yongan Pharmaceutical Co., Limited. Address: 18, Provincial Highway, 237 Huaian, Economic Development Zone, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (130401, 130402, 130501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Farxiga Tablet 5mg manufactured by AstraZeneca pharmaceutical (B# RF812, Mfg. date 11-2019, Exp. Date 10-2022) by performing quality tests (Identification, weight variation, Disintegration time & Assay.). Comparative Dissolution Profile has also been performed against the same brand that is Farxiga Tablet 5mg manufactured by AstraZeneca pharmaceutical (B# RF812, Mfg. date 11-2019, Exp. Date 10-2022) in 3 medias i.e; 0.1N HCl, Acetate Buffer pH4.5 & Phosphate Buffer pH 6.8.The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Name: Jiangsu Yongan Pharmaceutical Co., Limited. Address: 18, Provincial Highway, 237 Huaian, Economic Development Zone, Jiangsu, China.		
API Lot No.	7100-202006001		
Description of Pack (Container closure system)	Blue color round shaped, biconvex film coated tablets, having both sides plain packed in Alu-Alu Blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR20-010/T2/S1	RD/PR20-010/T2/S2	RD/PR20-010/T2/S3

Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	30-09-2020	30-09-2020	30-09-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted copy of Last inspection Report conducted on 24/01/2018 (Daclatasvir). The board granted the approval in 278th meeting held on 29-31 Jan 2018 of **Dasvir Tablet 60mg and 90mg**.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. JS2020921 issued by Jiangsu drug administration valid till 20/09/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No. ZY20061201G/W Dated 16/06/2020 for Dapagliflozin propanediol monohydrate attested by Assistant Director (I&E) DRAP, Lahore bearing batch number 7100-202006001.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.3	• Valid copy of DML of drug product manufacturer shall be submitted. • Latest GMP certificate/inspection report conducted within last three years of the finished product manufacturer shall be submitted.	Copy of valid DML w.e.f. 08-04-2021 is submitted. Copy of DML renewal inspection report is submitted by the firm wherein the panel recommends the renewal of DML to M/s Novamed Pharmaceuticals.
2.	1.5.4	Different pack sizes are mentioned in different parts of the application. 1.5.4 (14's, 28's) Covering letter has mentioned 4 different pack sizes. Clarification is required.	All the marketed pack sizes are applied to meet the market requirement on more economical values.
3.	2.3.R.2	Justify the dispensed quantity drug substance i.e. Dapagliflozin against the label claim.	Firm has submitted that quantity of dapagliflozin is calculated with respect to label claim & salt for a batch of 2000 tablets. Label claim = 5mg Factor = 1.23 6.15mg/ tablet 6.15 x 2000 = 0.013kg

			Executed BMR's have shown 6.5mg/tablet quantity while they are claiming 6.15mg/tablets.
4.	3.2.S.4.2.	• Proposed chromatographic conditions i.e. mobile phase and diluent are different between the analytical method proposed by the drug substance manufacturer and drug product manufacturer for the assay test of dapagliflozin. Clarification is required.	Firm has submitted that we brought some changes in the method for our feasibility but to ensure repeatability results we have validated the changed method as per international guidelines using USP/ICH.
5.	3.2.S.4.3	• Accuracy parameter of the verification studies of drug substance provided by the drug product manufacturer is for some other molecule than applied molecule. Clarification is required.	Firm has submitted that there was typo error in the report which has been amended.
6.	3.2.S.4.4	Provide results of analysis of relevant batch(es) of Dapagliflozin propanediol monohydrate performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacture.	Firm has provided COA for the drug substance. ***COA of the drug substance provided by the drug product manufacturer has different manufacturing date, Expiry date from that of the drug substance manufacturer.*** ***Furthermore, the manufacturing date of the drug substance is June 2021 while the drug product manufacturer has conducted analysis on 17-08-2020.***
7.	3.2.P.1	• Colloidal silicon dioxide is mentioned as active ingredient in the composition. Clarification is required. • Qualitative composition of the applied formulation is different from innovator product. Reference product does not contain SLS while the applied formulation has SLS as inactive. Clarification is required.	Firm has submitted that colloidal silicon dioxide is erroneously mentioned as active. It is used as glidant in manufacturing of dapagliflozin. Firm has submitted that SLS is excipient and the chemical combability studies are carried out for all excipients used in the formulation, where no interference is observed. Also, the satisfactory stability studies show that all excipients are chemically compatible.
8.	3.2.P.2.2.1	• Raw data sheets of content uniformity test in pharmaceutical equivalence has pyridoxine HCl. Clarification is required. • Dissolution test has not been performed in the pharmaceutical equivalence. Clarification is required. • Manufacturing date and expiry date of the same batch of innovator product are different. Clarification is required.	Firm has submitted new sheets for content uniformity wherein dapagliflozin is mentioned. Firm has submitted that CDP was performed against the innovator product and pharmaceutical equivalence was established through CDP and rest of the parameters are covered under pharmaceutical equivalence. Firm has submitted revised sheets for manufacturing and expiry dates of the innovator product.
9.	3.2.P.3.5	This section has mentioned specifications for pyridoxine & doxylamine. Clarification is required.	Firm has submitted revised process validation protocol for dapagliflozin.
10.	3.2.P.5.1	• Justify dissolution limits i.e., NLT 80% (Q) in 45 minutes in 0.1N HCL, medium volume (500ml) & Speed (50rpm) since innovator product (Farxiga) specifies NLT (Q) in 15 min	Firm has submitted that as per FDA's dissolution guidelines 2018their dissolution conditions are well complied with the conditions mentioned in the guidance document for paddle

		in acetate buffer 4.5 pH with medium volume of 1000ml & speed of 60 rpm. Clarification is required. • Accuracy parameter of the validation report/studies for drug product provided by the drug product manufacturer is for some other molecule than applied molecule. Clarification is required.	apparatus. They further submitted that their current dissolution limit is 30 minutes instead of 45 minutes. They further submitted that after reviewing the dissolution release trend in CDP report it is evident that more than 80% drug is released in 15 minutes so we are revising our current acceptance specification limit to NLT 80% in 15 minutes instead of 30 minutes. ***Drug product specifications has mentioned 45 minutes for dissolutions of the drug product.*** ***Furthermore, not only the time limit but also the dissolution medium, medium volume and paddle speed all are different from the innovator product.*** Firm has submitted revised analytical method validation report wherein they have mentioned dapagliflozin.
11.	3.2 P.8	Reference of previous approval of applications with stability study data of the firm shall be submitted.	The firm has submitted copy of inspection Report conducted on 22/01/2018 for Dasvir 60mg and Dasvir 90mg (Daclatasvir).
12.	3.2.P.8.1	Submit stability data sheets as per approved format by the Registration Board with inclusion of API lot number.	Firm has submitted new stability sheets for the stability data wherein they have included API lot No. in the new sheets. ***However, the API lot No. mentioned in the new data sheets and API lot No. in COA, import document are different from each other.***

Decision: Registration Board decided to defer the case for the following points:

- **Justify the dispensed quantity drug substance i.e. Dapagliflozin against the label claim as Label claim is 5mg and after factor calculation (1.23) each tablet will have 6.15mg of Dapagliflozin while the Executed BMR's have shown 6.5mg/tablet quantity for Dapagliflozin.**
- **Justify dissolution limits i.e., NLT 80% (Q) in 45 minutes in 0.1N HCL, medium volume (500ml) & Speed (50rpm) since innovator product (Farxiga) specifies NLT (Q) in 15 min in acetate buffer 4.5 pH with medium volume of 1000ml & speed of 60 rpm.**
- **Justification shall be submitted regarding the API lot No. mentioned in the new stability data sheets and API lot No. in COA, import document are different from each other.**
- **Justification regarding the COA of the drug substance provided by the drug product manufacturer shall be submitted as it has different manufacturing date, Expiry date from that of the drug substance manufacturer. Furthermore, the manufacturing date of the drug substance is June 2021 while the drug product manufacturer has conducted analysis on 17-08-2020.**

426.	Name, address of Applicant / Marketing Authorization Holder	M/s Novamed Pharmaceuticals (Pvt.) Ltd., 28km Ferozepur Road Lahore.
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt.) Ltd., 28km Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23875 dated 31-08-2021.
	Details of fee submitted	PKR 30,000/-: dated 07-06-2021.
	The proposed proprietary name / brand name	Dapaflo 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin …… 10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors.
	Reference to Finished product specifications	In-House
	Proposed Pack size	14's, 28's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA® 10mg (dapagliflozin) film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Xiga 10mg tablets, CCL Pharmaceuticals, Reg. No. 090505.
	GMP status of the Finished product manufacturer	License granted on 08/04/2006 and renewed on 08/04/2021 General tablet section approved and GMP certificate on 31/08/2021.
	Evidence of section approval.	Tablet section as per GMP certificate.
	Name and address of API manufacturer.	Name: Jiangsu Yongan Pharmaceutical Co., Limited. Address: 18, Provincial Highway, 237 Huaian, Economic Development Zone, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions:

		Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (130401, 130402, 130501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Farxiga Tablet 10mg manufactured by AstraZeneca pharmaceutical (B# RB164, by performing quality tests (Identification, weight variation, Disintegration time, content uniformity & Assay). Comparative Dissolution Profile has also been performed against the same brand that is Farxiga Tablet 10mg manufactured by AstraZeneca pharmaceutical (B# RB194, Mfg. date 06-2019, Exp. Date 05-2021) in 3 medias i.e; 0.1N HCl, Acetate Buffer pH4.5 & Phosphate Buffer pH 6.8.The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Name: Jiangsu Yongan Pharmaceutical Co., Limited. Address: 18, Provincial Highway, 237 Huaian, Economic Development Zone, Jiangsu, China.		
API Lot No.	7100-202006001		
Description of Pack (Container closure system)	Peach color round shaped, biconvex film coated tablets, having breaking line on one side and other side is plain.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR20-011/T2/S1	RD/PR20-011/T2/S2	RD/PR20-011/T2/S3
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	30-09-2020	30-09-2020	30-09-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted copy of Last inspection Report conducted on 24/01/2018 (Daclatasvir), 06/03/2017 (Sofosbuvir)

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. JS2020921 issued by Jiangsu drug administration valid till 20/09/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No. ZY20061201G/W Dated 16/06/2020 for Dapagliflozin propanediol monohydrate attested by Assistant Director (I&E) DRAP, Lahore bearing batch number 7100-202006001.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.3	• Valid copy of DML of drug product manufacturer shall be submitted. • Latest GMP certificate/inspection report conducted within last three years of the finished product manufacturer shall be submitted.	Copy of valid DML w.e.f. 08-04-2021 is submitted. Copy of DML renewal inspection report is submitted by the firm wherein the panel recommends the renewal of DML to M/s Novamed Pharmaceuticals.
2.	1.5.4	Different pack sizes are mentioned in different parts of the application. 1.5.4 (14's, 28's) Covering letter has mentioned 4 different pack sizes. Clarification is required.	Firm has submitted that all the marketed pack sizes are applied to meet the market requirement on more economical values.
3.	2.3.R.2	Justify the dispensed quantity drug substance i.e. Dapagliflozin against the label claim.	Firm has submitted that quantity of dapagliflozin is calculated with respect to label claim & salt for a batch of 2000 tablets. Label claim = 10mg Factor = 1.23 12.3mg/ tablet 12.3 x 2000 = 0.024kg ***Executed BMR's have shown 13.05 mg/tablet quantity while they are claiming 12.3mg/tablets.***
4.	3.2.S.4.2.	Proposed chromatographic conditions i.e. mobile phase and diluent along with concentration of sample and standard solution are different between the analytical method proposed by the drug substance manufacturer and drug product manufacturer for the assay test of dapagliflozin. Clarification is required.	Firm has submitted that we brought some changes in the method for our feasibility but to ensure repeatability results we have validated the changed method as per international guidelines using USP/ICH.
5.	3.2.S.4.4	Provide results of analysis of relevant batch(es) of Dapagliflozin propanediol monohydrate performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of	Firm has provided COA for the drug substance. ***COA of the drug substance provided by the drug product manufacturer has different manufacturing date, Expiry***

		Analysis (CoA) of the same batch from Drug Substance manufacture.	***date from that of the drug substance manufacturer.*** ***Furthermore, the manufacturing date of the drug substance is June 2021 while the drug product manufacturer has conducted analysis on 17-08-2020.***
6.	3.2.P.1	• Colloidal silicon dioxide is mentioned as active ingredient in the composition. Clarification is required. • Qualitative composition of the applied formulation is different from innovator product. Reference product does not contain SLS while the applied formulation has SLS as inactive. Clarification is required.	Firm has submitted that colloidal silicon dioxide is erroneously mentioned as active. It is used as glidant in manufacturing of dapagliflozin. Firm has submitted that SLS is excipient and the chemical combability studies are carried out for all excipients used in the formulation, where no interference is observed. Also, the satisfactory stability studies show that all excipients are chemically compatible.
7.	3.2.P.2.2.1	• Raw data sheets of content uniformity test in pharmaceutical equivalence has pyridoxine HCl. Clarification is required. • Dissolution test has not been performed in the pharmaceutical equivalence. Clarification is required.	Firm has submitted new sheets for content uniformity wherein dapagliflozin is mentioned. Firm has submitted that CDP was performed against the innovator product and pharmaceutical equivalence was established through CDP and rest of the parameters are covered under pharmaceutical equivalence.
8.	3.2.P.5.1	• Justify dissolution limits i.e., NLT 80% (Q) in 30 minutes in 0.1N HCL, medium volume (500ml) & Speed (50rpm) since innovator product (Farxiga) specifies NLT (Q) in 15 min in acetate buffer 4.5 pH with medium volume of 1000ml & speed of 60 rpm. Clarification is required.	Firm has submitted that as per FDA's dissolution guidelines 2018their dissolution conditions are well complied with the conditions mentioned in the guidance document for paddle apparatus. They further submitted that their current dissolution limit is 30 minutes instead of 45 minutes. They further submitted that after reviewing the dissolution release trend in CDP report it is evident that more than 80% drug is released in 15 minutes so we are revising our current acceptance specification limit to NLT 80% in 15 minutes instead of 30 minutes. ***Drug product specifications has mentioned 45 minutes for dissolutions of the drug product.*** ***Furthermore, not only the time limit but also the dissolution medium, medium volume and paddle speed all are different from the innovator product.***
9.	3.2 P.8	• Reference of previous approval of applications with stability study data of the firm shall be submitted. • COA of drug substance i.e. Dapagliflozin propanediol monohydrate, B# 7100-202006001 shall be submitted.	The firm has submitted copy of inspection Report conducted on 22/01/2018 for Dasvir 60mg and Dasvir 90mg (Daclatasvir). Submitted.

10.	3.2.P.8.1	Submit stability data sheets as per approved format by the Registration Board with inclusion of API lot number.	Firm has submitted new stability sheets for the stability data wherein they have included API lot No. in the new sheets. ***However, the API lot No. mentioned in the new data sheets and API lot No. in COA, import document are different from each other.***

Decision: Registration Board decided to defer the case for the following points:

- **Justify the dispensed quantity drug substance i.e. Dapagliflozin against the label claim as Label claim is 10mg and after factor calculation (1.23) each tablet will have 12.3mg of Dapagliflozin while the Executed BMR's have shown 13.05 mg/tablet quantity for Dapagliflozin.**
- **Justify dissolution limits i.e., NLT 80% (Q) in 45 minutes in 0.1N HCL, medium volume (500ml) & Speed (50rpm) since innovator product (Farxiga) specifies NLT (Q) in 15 min in acetate buffer 4.5 pH with medium volume of 1000ml & speed of 60 rpm.**
- **Justification shall be submitted regarding the API lot No. mentioned in the new stability data sheets and API lot No. in COA, import document are different from each other.**
- **Justification regarding the COA of the drug substance provided by the drug product manufacturer shall be submitted as it has different manufacturing date, Expiry date from that of the drug substance manufacturer. Furthermore, the manufacturing date of the drug substance is June 2021 while the drug product manufacturer has conducted analysis on 17-08-2020.**

Registration applications of Imported products on Form 5 F.

427.	Name, address of Applicant / Importer	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
	Details of Drug Sale License of importer	License No: 1126. Address: B-23-C, S.I.T.E., Karachi-75700, Pakistan Address of Godown: AGP Limited, B-23-C, S.I.T.E., Karachi. Validity: 21-09-2021. Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of wholesale by of manufacturer, importer or indenter.
	Name and address of marketing authorization holder (abroad)	Mylan Laboratories Limited, Plot No. H-12 & H-13, MIDC, Waluj, Aurangabad 431136, Maharashtra state, India.
	Name, address of manufacturer(s)	M/s Mylan Laboratories Limited, Plot no. H-12 & H-13, MIDC, Waluj, Aurangabad -431136, Maharashtra state, India
	Name of exporting country	India.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP certificate (No. COPP/CERT/AD/90474/2020/11/31606/159456) dated 11-Apr-2020 issued by Food and Drug Administration Maharashtra State Mumbai, India for DOVPRELA-200mg (Pretomanid Tablets 200mg). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 17-Dec-2021. **GMP:** Copy of GMP certificate No. NEW-WHO-GMP/CERT/AD/72573/2018/11/26257 in the name of M/s Mylan Laboratories Limited, Plot no. H-12 & H-13, MIDC, Waluj, Aurangabad -431136, Maharashtra state, India issued by Food and Drug Administration, M.S.

		Bandra-Kurla complex Bandra (E), Mumbai Maharashtra India valid till 17-12-2021 is submitted by the applicant. Firm has also submitted notarized copy of GMP Certificate No. 18368 in the name of M/s Mylan Laboratories Limited, Plot No. H-12 & H-13, MIDC, Waluj Industrial Estate, Aurangabad, India issued by HPRA Ireland on the basis of inspection conducted on 17-11-2017 valid for three years. **WHO Prequalification:** The product is WHO prequalified (Reference Number: TB386 (a).
	Details of letter of authorization / sole agency agreement	**Letter of Authorization:** Firm has submitted original, legalized & product specific letter of Authorization from Mylan Laboratories Limited, having its corporate office at House No. 8-2-293/82/J-III, Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad, India. The letter specifies that the manufacturer appoints M/s AGP Limited, B-23-C, S.I.T.E., Karachi to register their products in Pakistan. The authorization letter is valid till 16-Apr-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26352: 22-09-2021.
	Details of fee submitted	PKR 50,000/-: 09-07-2020.
	The proposed proprietary name / brand name	Dovprela 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Pretomanid …….200mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Nitroimidazooxazine Antimycobacterial drug (As per dossier). J04 Antimycobacterials. (As per ATC code) Limited Population: Pretomanid Tablet is an Antimycobacterials indicated, as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB). Approval of this indication is based on limited clinical safety and efficacy data. This drug is indicated for use in a limited and specific population of patients.

	Reference to Finished product specifications	In house
	Proposed Pack size	HDPE Bottle (26 Tablets)
	Proposed unit price	No information provided.
	The status in reference regulatory authorities	Pretomanid Tablet 200mg, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Mylan Laboratories Limited (Unit-9), Plot No. 5, Road No.12, J.N. Pharma City, Tadi Village Parawada Mandal, Visakhapatnam, Andhra Pradesh, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated for 06 months as well as real time conditions for 24 months. The real time stability data is conducted at 25^{o}C ± 2^{o}C, RH 60% ± 5% and accelerated stability data is conducted at 40^{o}C ± 2^{o}C, RH 75% ± 5%. (Batch No. 27083789, 27083790 & 27083791)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted complete data of formulation development process. Dovprela 200mg Tablet (Pretomanid) is Innovator Product, therefore, firm has submitted detailed Module 4 and Module 5.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle pack
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40^{o}C ±2^{o}C / 75% ± 5% RH for 6 months (Batch No. 2014678, 2014679 & 2014680).

		The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH for 24 months (Batch No. 2014678, 2014679 & 2014680).

Evaluation by PEC:

S. No.	Section	Observation	Remarks by the evaluator
1.	1.1	Fee of 75,000/- shall be submitted.	Firm has submitted differential fee of 25000/- vide slip No. 8216477734 dated 15-07-2022.
2.	1.3.2	Valid copy of GMP of the finished product manufacturer.	Notarized and legalized GMP certificate No. NEW-WHO-GMP/CERT/AD/106169/2022/11/38759 in the name of M/s Mylan Laboratories Limited, Plot no. H-12 & H-13, MIDC, Waluj, Aurangabad -431136, Maharashtra state, India issued by Food and Drug Administration, M.S. Bandra-Kurla complex Bandra (E), Mumbai Maharashtra India valid till 11-01-2025 is submitted by the applicant.
3.	1.3.4	Valid copy of DSL of the applicant shall be submitted.	Firm has submitted new copy of DSL valid till 21-09-2023.
4.	3.2.S.7.3	Real time stability data of drug substance is conducted at 25ºC ± 2ºC, RH 60% ± 5% justification is required.	Firm has submitted new stability studies of the drug substance for the same batches at 30ºC ± 2ºC, RH 75% ± 5%.
5.		Valid & legalized copy of CoPP shall be submitted.	Firm has submitted valid legalized & notarized CoPP No. COPP/CERT/AD/110377/2022/11/39211/190611 for Dovprela 200mg tablets. The submitted copy of CoPP valid till 11-01-2025.
6.		Packing provided by the applicant has manufacturing address other than the specified in GMP and other document.	Firm has submitted that Dovprela is a WHO prequalified product and is manufactured in two plants by principal manufacturer and the data/specification are common for both plants. The product is imported from Maylan Aurangabad plant which is WHO approved plant for this product. The document provided for the packing/container closure system is made by Maylan Nashik plant but these are also applicable for maylan Aurangabad plant. These documents are also stamped by QA of Maylan Aurangabad plant.

Decision: Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

428.	Name, address of Applicant / Importer	M/s Hakimsons Private Limited., A-58/B, S.I.T.E, Karachi-75700, Pakistan.
	Details of Drug Sale License of importer	**License No:** 001 No. DHOKW (Drugs)/-0431 **Address:** A-58/B, S.I.T.E, Karachi **Validity:** 21-08-2022 **Status:** Drug sale license by the way of wholesale by of a manufacturer, importer or indenter.
	Name and address of marketing authorization holder (abroad)	M/s Eugia Pharma Specialties Limited, Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri, District Telangana, 500101, India.

	Name, address of manufacturer(s)	M/s Eugia Pharma Specialties Limited, Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri, District Telangana, 500101, India.
	Name of exporting country	India.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**<u>CoPP:</u>** Firm has submitted Original Legalized CoPP (Certificate#2850/STORES/2020-40) issued by Drugs Control Administration, Government of Telangana, India for PACSITA 500 (Capecitabine Tablets USP 500mg). CoPP confirms facilities and operations conforming to GMP as recommended by the World Health Organization. The certificate is valid till 10-06-2021. CoPP certificate has also mentioned name of applicant for certificate, if different from license holder that is M/s Aurobindo Pharma Limited, plot No.2, Maitri Vihar, Ameerpet, Hyderabad, Telangana, India. ***However, the CoPP certificate has mentioned that this product is not actually on the market of the exporting country.*** **<u>GMP certificate:</u>** The firm has submitted legalized copy of GMP certificate dated 11-06-2018 for M/s Eugia Pharma Specialties Limited, Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri, District Telangana, 500101, India issued by Drugs control Administration, Government of Telangana, India. Certificate has mentioned that manufacturer conforms to the requirement for Good manufacturing Practices in the manufacturing and quality control for 17 products for export in the international market. The certificate is valid till 11-06-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted a copy of letter of authorization from M/s Aurobindo Pharma Limited, plot No.2, Maitri Vihar, Ameerpet, Hyderabad having its manufacturing plant at M/s Eugia Parma Specialties Limited, Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri District, Telangana, India. According to the letter, the firm has appointed "M/s Hakimsons Pvt. Ltd," with principal place of business at A-58/B, S.I.T.E, Manghopir Road, Karachi as its Exclusive Distributor for the territory of Islamic Republic of Pakistan. The letter was issued on 10-12-2020 and it is valid for a period of five years. The applicant has submitted notarized copy of letter clarifying the relationship between Eugia pharma specialties Limited, and Aurobindo Pharma Ltd., Eugia pharma specialties Limited is wholly owned subsidiary company of Aurobindo Pharma Limited with registered office address "Plot No.2, Maitrivihar, Ameerpet, Hyderabad, Telangana State, India. Eugia pharma specialities Limited, with manufacturing site address "survey no. 550, 551 & 552, Kolthur village, Shamirpet Mandal, Medchal -Malkagiri District, Telangana, India, manufactures oncology & Hormonal

		products and is one of the manufacturing facilities associated with Aurobindo Pharma Limited.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 24702: dated: 07/09/2021.
	Details of fee submitted	PKR 100,000/-: 04/02/2021.
	Proposed proprietary name / brand name	PACSITA 500 mg tablets.
	Strength/concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Capecitabine ……...…….. 500 mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antineoplastic agents. (ATC code: L01BC06)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	XELODA (capecitabine) film coated tablets 500mg, USFDA approved.
	For generic drugs (me-too status)	Relicitabine Tablets 500mg by M/s Helix Pharma, Reg. No. 088875.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Name, address of drug substance manufacturer	M/s Divi's Laboratories Limited, Unit-2, Chippada (V), Annavaram Post Bheemunipatnam (M) Visakhapatnam District Andhra Pradesh, India.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 03 batches for drug substance at accelerated conditions i.e. 40 ± 2° C / 75 ± 5% RH for 06 months as well as real time stability data at 30 ± 2° C/65 ± 5%RH for 60 months. Batch No. (2-WS3O001, 2-WS-3O002 & 2-WS-3O003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence with reference product i.e. Xeloda 500mg by Hoffman La Rosch Inc. USA, B. No. X3148XI by performing the following quality test; Description, Average weight of the tablets, Disintegration time, Water by KF, impurities and Assay. Firm has also submitted CDP results against the same reference product i.e. Xeloda 500mg by Hoffman La Rosch Inc. USA, B. No. X3993XI in three different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer & pH 6.8 Phosphate buffer (USP-II (Paddle), 500ml & 75 RPM) and similarity factor is comparable.
	Analytical method validation/verification of product	Firm has submitted Assay Method Validation Protocols along with Reports of Capecitabine Tablets 500mg Finished product as well as for Active substance. USP analytical test methods were developed to determine the identification (By HPLC), Assay (By HPLC), Related substance (By HPLC), R-Enantiomer content (by HPLC), and color absorbance (By UV) in drug product and methods have been validated as per the ICH.
	Container closure system of the drug product	PVC/PVDC – Aluminum foil blister pack
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 06 months. The real time stability study data is conducted at 30°C ±2°C /75% ± 5% RH. The real time stability study data of 03 batches is for 24months. Batch No. (CB5016001-B, CB5016002-B & CB5016003-B) Batch size: 60,000 Tablets each. Mfg. Date: 09 - 2016 Stability initiation date: 14-10-2016

Evaluation by PEC:

Section	Observation	Response submitted by the firm.
1.1	Differential fee of 50,000/- shall be submitted.	Firm has submitted a differential fee of 50000/- vide slip No. 65206501965 dated 27-07-2022.
	• Notarized copy of the agreement shall be submitted.	Firm has submitted colored copy of the agreement and further submitted that original notarized agreement is submitted in the dossier of Brotoma injection 3.5mg.
	• CoPP confirming the status of the product in exporting country that the product is actually not on the market for sale. Clarification is required.	Firm has referred to the decision of registration Board in its 256th meeting stating as under: ""if an imported drug is not on free sale in its respective country of origin / manufacture, such product will be registered in Pakistan if the product manufactured in the applied facility is approved by any of the regulatory authorities from USFDA, EMA, PMDA Japan, Australia TGA, Health Canada, Switzerland or any of regulatory authority of former erstwhile Westren Europe (United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland and Spain) or three stringent regulatory bodies of former erstwhile Eastren Europe. However, references countries regarding availability of drug / molecule / formulation shall remain the same as specified in 249th meeting of Registration Board." In this context firm has referred to the following product approved by US FDA: "Capecitabine 500mg tablet (Application no. A210604) of M/s Eugia pharma Specialties Ltd.," verified form following web links of official websites of US FDA: https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=56441153-a1e5-4fdc-96d6-f21baa6b5fbe The manufacturing site of above cited product has also been verified as M/s EUGIA Pharma Specialities Limited, Sy.No.550, 551 & 552, Kolthur Village, Shameerpet Mandal, Medchal-Malkajgiri District, Medchal, Telangana 500101, India (IND), from the following web link of US FDA: https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm
	• Valid GMP certificate of the finished product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate dated 26-11-2021 for M/s Eugia Pharma Specialties Limited, Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri, District Telangana, 500101, India issued by Drugs Control Administration, Government of Telangana, India. Certificate has mentioned that manufacturer conforms to the requirement for Good Manufacturing Practices in the manufacturing and quality control for 17 products for export in the international market.

		The certificate is valid till 25-11-2024.
1.5.22	Good pharmacovigilance procedure is for Helix pharma	Firm has submitted new document of Hakimsons (Pvt.) Limited.
3.2.S.4.3	Drug substance verification studies performed by finished product manufacturer shall be submitted.	Firm has submitted verification studies of the drug substance performed by the drug product manufacturer.
3.2.P.2.2	In CDP results at 4.5 pH Acetate buffer, the value of F2 is less than 50 at 50 RPM. Clarification shall be submitted.	Firm has submitted that from the dissolution profile it can be seen that the test product dissolution profile is having high %RSD at initial time points i.e. more than 10% even up to 20-minute time point and thereby statistical calculation of f2 value is not feasible or applicable. Since the observed dissolution % RSD is high for the dissolution when tested at agitation speed of 50 RPM for paddle (USP apparatus II), it was decided to generate the dissolution profile at the agitation speed of 75 RPM to reduce the %RSD. Hence the dissolution profile of Capecitabine tablets USP 500mg was generated at 75 RPM in pH 4.5 acetate buffer and %RSD is found satisfactory and low level for test product dissolution profile and the calculated statistical f2 value is adequate (more than 50). Hence it can be concluded that the generic product dissolution profile in pH 4.5 acetate buffer is comparable to the reference drug product.

Decision: Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs.

429.	Name, address of Applicant / Importer	M/s Al Habib Pharmaceuticals, Plot No. 81-B Block B, S.M.C.H.S, Karachi.
	Details of Drug Sale License of importer	License No: 1245. Address: 81-B Block B, S.M.C.H.S, Karachi. Address of Godown: 1. Plot No. 10 sector25 KIA, Karachi. 2. HT – 8, Landhi Industrial Area, Karachi. Validity: 18-05-2022. Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of wholesale by of manufacturer, importer or indenter.
	Name and address of marketing authorization holder (abroad)	Laboratories IMA S.A.I.C. Palpa 2862, Ciudad Autonoma de Buenos Aires, Argentina. (Laboratories IMA S.A.I.C. Palpa 2862, City of Buenos Aires Argentina Republic.)
	Name, address of manufacturer(s)	Laboratories IMA S.A.I.C. Palpa 2862, Ciudad Autonoma de Buenos Aires, Argentina. (Laboratories IMA S.A.I.C. Palpa 2862, City of Buenos Aires Argentina Republic.)
	Name of exporting country	Argentina.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**<u>CoPP:</u>** Firm has submitted copy of CoPP dated 13-10-2020 issued by National Institute of Drugs Avenida Caseros 2161 City of Buenos Aires Argentina Republic for PREMETREXED IMA (Pemetrexed 500 lyophilized powder for injection.) The CoPP confirms free sale status of the product in exporting country as well as

		GMP status of the manufacturing site through periodic inspection every two year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid for one year. **GMP:** Firm has submitted copy of GMP certificate in the name of Laboratories IMA S.A.I.C. Palpa 2862, City of Buenos Aires, Argentina Republic issued by the National Administration of Drugs, Food and medical Devices (ANMAT) through the National Institute of Drugs (INAME) issued on 13-04-2020 which states that the manufacturing facility at Palpa is subject to regular inspection to verify compliance with the Good Manufacturing practices according to the regulation in force in the Argentina Republic. Valid for 12 months. However, status of the finished product manufacturer has not been revealed whether compliant Good Manufacturing practices according to the regulation in force or otherwise.
	Details of letter of authorization / sole agency agreement	**Letter of Authorization:** Firm has submitted copy of letter of Authorization dated 22-10-2018 from M/s Laboratories IMA S.A.I.C. Palpa 2862, City of Buenos Aires, Argentina Republic for 11 products which also contain pemetrexed 500mg injection. The authorization letter is valid for five years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 24062: 01-09-2021.
	Details of fee submitted	PKR 150,000/-: 26-08-2021.
	The proposed proprietary name / brand name	Pemex 500mg injection.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Pemetrexed as disodium hemi pentahydrate …… 500mg
	Pharmaceutical form of applied drug	Lyophilized powder for injection.
	Pharmacotherapeutic Group of (API)	Antineoplastic Agents ATC code: L01BA04
	Reference to Finished product specifications	Pharma Europa Volume 23.
	Proposed Pack size	1's.
	Proposed unit price	As per Policy.

	The status in reference regulatory authorities	ALIMTA (pemetrexed for injection) 500mg, USFDA Approved.
	For generic drugs (me-too status)	Almita 500mg injection, Eli Lilly Pakistan, Reg. No. 043068.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Shandong Boyuan Pharmaceutical Co. Ltd., Qinjiang Street, Jibai Economic Development Zone, Jinan City, Shandong Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated for 06 months as well as real time conditions for 24 months. The real time stability data is conducted at 5 ^{o}C ± 3^{o}C, and accelerated stability data is conducted at 25^{o}C ± 2^{o}C, RH 60% ± 5%. (Batch No. 1001KL61C, 1002KL61C & 1003KL61C)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against reference product i.e. Almita by ELI LILLY by performing the following tests; Appearance, pH, Reconstituted solution, water content (Karl Fischer), bacterial endotoxin, related substances, particulate matter and Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I colourless glass vial with Bromo butyl elastomeric stopper and aluminium seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40^{o}C ±2^{o}C / 75% ± 5% RH for 6 months (Batch No. 27001, 27002 & 27003). The real time stability study data is conducted at 30^{o}C ±2^{o}C / 75% ± 5% RH for 24 months (Batch No. 27001, 27002 & 27003).

Evaluation by PEC:

S. No.	Section	Observation	Remarks by the evaluator
1.	1.3.4	Valid copy of Drug Sale License of the applicant shall be submitted.	Attested copy of Drug Sale License No. 0230 18-05-2022 in the name of Al Habib Pharmaceuticals 81-B Block B, S.M.C.H.S, Karachi is submitted by the firm.
2.		• Valid and notarized GMP certificate of the finished product manufacturer shall be submitted. • Valid and notarized copy of CoPP shall be submitted.	Firm has submitted copy of GMP certificate issued on 03-04-2022 valid for one year. Firm has also provided copy of CoPP dated 13-10-2021 for the product i.e. Pemetrexed (disodium hemi pentahydrate) 500mg valid for one year. Firm further submitted that the CoPP that we submitted with the dossier was having validity till October, 2021 and as it gets expired during its period in R&I that's why as per rule it will be considered as valid as we received R&I attested letter on 1st September, 2021. ***Neither GMP certificate nor CoPP is notarized and countersigned by the embassy of Pakistan.***
3.	1.3.8	Site master file and credentials of the manufacturer shall be submitted.	Submitted.
4.	3.2.S	Drug substance document has mentioned Heptahydrate while the label claim has mentioned Hemi penta hydrate. Clarification is required.	Firm has submitted new DMF for Pemetrexed disodium hemi penta hydrate.
5.	3.2.S.4.1	• Water content mentioned in the specifications of the drug substance is 8.2% - 10.2% while the monograph has mentioned 19.55 to 22.1%. Clarification is required. • Assay content is 97.5% to 102% in monograph while specifications has mentioned 98-102. Clarification is required.	Firm has submitted new DMF for Pemetrexed disodium hemi penta hydrate wherein the specification of the drug substance mentioned are E.P/USP. Firm has submitted that although the limits are different from official monograph but the values are within the limit of the official monograph.
6.	3.2.S.4.2	Also, the acetate buffer condition in the assay test are different from the monograph.	New DMF has the same conditions as mentioned in USP.
7.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial by the finished product manufacturer shall be submitted.	Analytical Method Verification studies performed by the IMA laboratories are submitted.
8.	3.2.S.4.4	• Batch analysis of the drug substance is for Qilu pharmaceutical Co., Ltd. Justification is required. • COA of primary / secondary reference standard including source and lot number shall be provided.	Firm has submitted COA for the drug substance from Shandong Boyuan Pharmaceutical Co., Ltd. Firm has also submitted COA of the primary / secondary reference standard.

9.	3.2.P.5.1	• In section 1.5 firm has claimed Ph. Eur. specifications for the finished drug product. Provided evidence of official monograph of the European pharmacopoeia for the applied formulation. • Justification shall be submitted for finished product specifications as general considerations of USP references for injections and ICH guidelines are followed while the official monograph is available in USP.	Firm has submitted that it was typographic error and the finished dosage form is having USP specifications. Firm has submitted that the dossier was prepared in 2018 and at that time the official monograph was pending and become part of official USP in 2020 that's why the specifications were developed via general chapter. They further submitted that the same specifications are part of the official monograph of pemetrexed. That's why the same is followed.
10.	3.2.P.8	Assay limits in the real time stability of B. No. 27003 at third month time point is out of specifications. Clarification is required.	Firm has submitted that it may be typo or misprinting error. They also submitted rectified/new stability data sheets.

Decision: Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs with innovator's specifications.

- **Registration letter will be issued after submission of valid, notarized & legalized CoPP certificate and valid, notarized & legalized GMP certificate for the finished product manufacturer.**
- **Firm will also submit fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

430.	Name, address of Applicant / Importer	M/s Medi Mark Pharmaceuticals, Liaqat Chowk, Sahiwal, Pakistan.
	Details of Drug Sale License of importer	DSL NO. **02-367-0154-049333D** Address: M/s Medi Mark Pharmaceuticals, Karbala Road House No. 588 Sahiwal. Go-down address: Nil. Valid up to 20-12-2021. Status: License to sell drugs as distributor.
	Name and address of marketing authorization holder (abroad)	M/s Shanghai Starry Pharmaceutical Co., Ltd., No. 500, Maoye Road, Jinshan Industrial Zone, Shanghai, China.
	Name, address of manufacturer(s)	M/s Shanghai Starry Pharmaceutical Co., Ltd., No. 500, Maoye Road, Jinshan Industrial Zone, Shanghai, China.
	Name of exporting country	China.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Detail of certificates attached (CoPP, GMP certificate) **CoPP:** Firm has submitted original legalized CoPP (certificate No. Shanghai20210001) dated 08-01-2021 issued by Shanghai Medical Products Administration, 728 Yisan Road, Shanghai China. The document confirms that the applied product strength is actually on the market in exporting country. The document also confirms that the facilities and operations also confirm to the requirement of Chinese's GMP. Valid up to 07-01-2023. **GMP:** Firm has submitted a document from Shanghai Medical Products Administration, addressed to M/s Shanghai Starry Pharmaceutical Co., Ltd., wherein it is informed that we organized an on-site inspection for the Large Volume parenteral (LVP) of your company located in No. 500, Maoye Road, Jinshan Industrial Zone, Shanghai, China from 10-12-2019 to 12-12-

		2019 and the inspection result meet the requirement of cGMP (25-02-2020).
	Details of letter of authorization / sole agency agreement	**Letter of Authorization:** Firm has submitted original, notarized & legalized sole agency agreement dated 22-03-2021 wherein M/s Shanghai Starry Pharmaceutical Co., Ltd., No. Maoye Road, Jinshan Industrial Zone, Shanghai, China has authorized M/s Medi Mark Pharmaceuticals, Liaqat Chowk, Sahiwal, Pakistan as their sole agent in order to register, sell and distribute Iohexol injection 350mg (Iodine/ml) 100ml in the territory of Pakistan. Validity of the agreement is for five years unless terminated by three months advance notice by either party.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 25214: dated 10-09-2021.
	Details of fee submitted	PKR 150,000/-: dated 26-08-2021.
	The proposed proprietary name / brand name	Hexol Injection 100ml.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contain; 75.5gm of Iohexol equivalent to 35gm of Iodine (350mg Iodine/ml)
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	X-RAY CONTRAST MEDIA, IODINATED ATC code: V08A.
	Reference to Finished product specifications	Ch. P specifications.
	Proposed Pack size	100ml glass infusion bottle, 10 bottles/box.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	OMNIPAQUE 350 mg iodine/mL (755 mg of Iohexol/mL), USFDA approved.
	For generic drugs (me-too status)	Kopaq 350mg/ml IV solution for injection, Punjab Medical Services, Reg. No. 097360.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

		The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacturer, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Name, address of drug substance manufacturer	M/s Zhejiang Starry Pharmaceutical Co. Ltd., No. 1 Starry Road of Xianju Modern Industrial Centralization Zone Xianju, Zhejiang, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at accelerated condition for 06 months as well as real time conditions for 24 months. The real time stability data is conducted at 25°C ± 2°C, RH 60% ± 5% and accelerated stability data is conducted at 40°C ± 2°C, RH 75% ± 5%. (Batch No. C006-0802003, C006-0802004 & C006-0802005)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols`, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence data of their products against Omnipaque of GE Healthcare, B. No. 12909988 by performing the following tests; Appearance, Identification, pH, related compounds, insoluble particulate matter, Bacterial endotoxin, sterility, and Assay.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	Neutral borosilicate glass bottle and chlorinated butyl rubber stopper.
	Stability study data of drug product, shelf life and storage conditions	• 24 months real time stability data at 30°C ± 2°C / 65% ± 5% RH of 03 batches (A1810251, A1810271 & A1810291). • 06 month accelerated stability data 40°C ± 2°C / 75% ± 5% RH of 03 batches (A1810251, A1810271 & A1810291).

Evaluation by PEC:

Sr. No.	Section	Observation	Response by the firm

<table>
<tr><td>1.</td><td>1.3.3</td><td>Applicant is marked as manufacturer. Clarification is required.</td><td>Applicant has submitted new module I wherein they have provided corrected information.</td></tr>
<tr><td>2.</td><td>1.4</td><td>Section 1.4 is completely missing. All the information in section 1.4 shall be submitted.</td><td>Firm has submitted complete details of the section 1.4.</td></tr>
<tr><td>3.</td><td>1.5.1 – 1.5.8</td><td>Complete details from 1.5.1 to 1.5.8 shall be submitted.</td><td>Firm has submitted complete details of the section 1.5.1 to 1.5.8.</td></tr>
<tr><td>4.</td><td></td><td>CoPP has mentioned two different strengths of the active ingredients. Clarification is required. 100ml contain 35g Iohexol and 100ml contains 75.5gm iohexol. Clarification is required.</td><td>Firm has submitted that the strength of iohexol injection 350mg I/mL in China named 100mL:35g (I), as the strength is calculated by iodine (I). And in the composition, 100mL of iohexol injection 350mg
I/mL contains 75.5g of iohexol (the API). Please note that 75.5g of iohexol (C19H26I3N3O9) is equivalent to 35g of iodine (I). So, this is not a problem.</td></tr>
<tr><td>5.</td><td>3.2.S.4.2</td><td>Detailed analytical procedures for the drug substance by the finished product manufacturer shall be submitted.</td><td>Firm has submitted detailed analytical procedures for the testing of the drug substance by the finished product manufacturer i.e. M/s Shanghai Starry Pharmaceutical Co., Ltd., No. 500, Maoye Road, Jinshan Industrial Zone, Shanghai, China.</td></tr>
<tr><td>6.</td><td>3.2.S.4.3</td><td>Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial by the finished product manufacturer shall be submitted.</td><td>Firm has submitted Analytical Method Verification studies performed by the finished product manufacturer.</td></tr>
<tr><td>7.</td><td>3.2.S.4.4</td><td>Provide summarized results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer.</td><td>Submitted.</td></tr>
<tr><td>8.</td><td>3.2.S.7.3</td><td>Real time stability of drug substance as per Zone IV-a shall be submitted.</td><td>Firm has submitted that real time stability data of drug substance as per Zone IV-a is not available as Our API company, Zhejiang Starry, only conducted stability 25°C/60%RH for the global market. It is accepted by any other countries. Hope Pakistan can accept as well.</td></tr>
<tr><td>9.</td><td>3.2.P.5.1</td><td>Justification of specification has mentioned that final specifications of iohexol injection complies with relevant guidelines of ICH and China. However, the official monograph of the applied formulation is available in USP. Clarification is required.</td><td>Firm has submitted that for the specifications of Iohexol injection350mg Iodine/ml, the pharmacopoeial reference of analytical procedure is mainly Chinese Pharmacopoeia (Ch. P. 2020), and we have compared the acceptance criteria in Ch. P with USP and JP, to generate some relatively strict acceptance criteria for our products. They also provided a comparison table between their shelf life specifications and USP specifications.</td></tr>
<tr><td>10.</td><td></td><td>Comparison of specification of the finished product and USP pharmacopoeia</td><td><table><tr><td>Test</td><td>Ch. Phar.</td><td>USP</td></tr><tr><td>pH:</td><td>6.8 – 7.6</td><td>6.8 – 7.7</td></tr></table></td></tr>
</table>

			Bacterial Endotoxin	< 0.13 EU/100ml (I)	NMT 0.2 USP unit/50mg (I)
			Free iodide	NMT 35µg/ml	NMT 200µg/ml
			Related compounds	Same as USP	NMT 0.6% NMT 0.1%
			Assay	96.0%-105%	95.0% - 105%

Test item	Method		Our release specification	Our shelf-life specification	USP40 Monograph
Appearance	By visual		Clear, colourless to pale yellow liquid	Clear, colourless to pale yellow liquid	Clear, colourless to pale yellow liquid
Refractive index	Refractive index		1.4349～1.4448	1.4349～1.4448	-
Identification	HPLC		The retention times of the major peaks of the *sample solution* correspond to those of the *system suitability solution*, as obtained in the test for Related compounds 1	The retention times of the major peaks of the *sample solution* correspond to those of the *system suitability solution*, as obtained in the test for Related compounds 1	The retention times of the major peaks of the *sample solution* correspond to those of the *system suitability solution*, as obtained in the test for organic impurities
	UV-VIS		It exhibits a maximum between 243nm and 247nm.	It exhibits a maximum between 243nm and 247nm.	-
	TLC		The color and position of the main spot of the *test solution* should be the same as that of the *reference solution*	The color and position of the main spot of the *test solution* should be the same as that of the *reference solution*	-
	Physicochemical test		Violet vapors are evolved.	Violet vapors are evolved.	-
pH	Determination of pH		7.2～7.6	6.8～7.6	6.8～7.7
Color of solution	UV-VIS	400nm	NMT 0.220	NMT 0.240	-
		420nm	NMT 0.060	NMT 0.070	-
		450nm	NMT 0.030	NMT 0.035	-
Free iodide	Potentiometric titration		NMT 30µg/ml	NMT 60µg/ml	NMT 0.02%
Free aromatic amine	UV-VIS		NMT 0.05%	NMT 0.05%	-
Tromethamine	Potentiometric titration		0.85～1.57mg/ml	0.85～1.57mg/ml	-
Edetate calcium disodium	Chemical titration		0.08～0.12mg/ml	0.08～0.12mg/ml	-

Related compounds 1 (corresponds to the test for Organic Impurities of USP)	HPLC	O-alkylated compounds	NMT 0.6%	NMT 0.6%	NMT 0.6%
		Any other individual impurity	NMT 0.1%	NMT 0.1%	NMT 0.1%
		Total impurities (excluding O-alkylated compounds)	NMT 0.3%	NMT 0.3%	NMT 0.3%
Related compounds 2	TLC	Rf value greater than the principal spot obtained with *reference solution (b)*	ND	ND	-
		Impurity A	NMT 0.2%	NMT 0.2%	-
		Any other individual impurity	NMT 0.1%	NMT 0.1%	-
		total impurities	NMT 0.4%	NMT 0.4%	-
Related compounds 3	TLC	Rf value greater than the principal spot obtained with *reference solution (b)*	ND	ND	-
		Impurity A	NMT 0.2%	NMT 0.2%	-
		Any other individual impurity	NMT 0.1%	NMT 0.1%	-
		total impurities	NMT 0.4%	NMT 0.4%	-
Related compounds 4	TLC	Rf value greater than the principal spot obtained with *reference solution (b)*	ND	ND	-
		Impurity A	NMT 0.2%	NMT 0.2%	-
		Impurity B	NMT 0.2%	NMT 0.2%	-
		Any other individual impurity	NMT 0.1%	NMT 0.1%	-
		total impurities	NMT 0.4%	NMT 0.4%	-
Heavy metal	Determination of heavy metal		NMT 20ppm	NMT 20ppm	-
Bacterial endotoxin	Gelation method		< 0.13 EU/100mgI	< 0.13 EU/100mgI	< 0.20 EU/50mgI
Osmolality	Determination of Osmolality		605～739mOsmol/kg	605～739mOsmol/kg	-
Particulate matter	Light blockage method	≥10μm	NMT 25/ml	NMT 25/ml	NMT 6000/bottle
		≥25μm	NMT 3/ml	NMT 3/ml	NMT 600/bottle
Sterile	Membrane filter		Complies.	Complies.	Complies.
Assay	Potentiometric titration		96.0%～105.0%	96.0%～105.0%	95.0%～05.0%

Decision: Registration Board approved the product with USP specifications subject to compliance of current Import Policy for Finished Drugs.

- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Firm will also submit corrected, legalized and notarized CoPP certificate for the applied product.**

Registration applications of locally manufactured (Human) deferred drugs on Form 5F.

431.	Name, address of Applicant / Marketing Authorization Holder	M/s Davis Pharmaceutical Laboratories, Plot No. 121 industrial Triangle area, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11388; dated 14-04-2021.
	Details of fee submitted	PKR 50,000/-: dated 26-01-2021.
	The proposed proprietary name / brand name	Kerolac 30mg IV/IM Injection.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Ketorolac Tromethamine …….. 30mg
	Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoule
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1ml x 5's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	US FDA approved.
	For generic drugs (me-too status)	Tekac 30mg/ml Injection, Sami Pharmaceuticals, Reg. No. 092855.
	GMP status of the Applicant.	GMP certificate issued on 08-10-2020 on the basis of inspection conduct 01-10-2019.
	GMP status of the Finished product manufacturer	GMP certificate issued on 21-05-2019 on the basis of inspection conduct 23-4-2019, valid up to 22-04-2022.
	Evidence of section approval of the Finished product manufacturer.	Liquid ampoule (from GMP certificate.) Ampoule general vide letter No. F. 1-12/89-Lic (Vol-II) dated 23-07-2012.
	Name and address of API manufacturer.	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 O ± 2 O C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30OC ± 2 O C / 65% ± 5% RH for 60 months. (Batch No. KTM06130016, KTM06130017 & KTM06130018)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Toradol Ampoule 30mg, B. No. C2436, Mfg. date 01, 2020 by Barrett Hodgson by performing quality tests (Description, Identification, pH, Assay, Sterility, Bacterial endotoxin.)
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India		
API Lot No.	KM-0100918, KTM-180015 & KTM180015.		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	A-439	A-596	A-611
Batch Size	46,200 Ampoules	16,000 Ampoules	33,000 Ampoules
Manufacturing Date	05-2018	03-2019	03-2019
Date of Initiation	25-06-2018	22-04-2019	20-05-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India Valid till 25-06-2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted attested copy of invoice (invoice# SCL2018/18-19 dated 29-01-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section Number	Observations	Firm's Response
1	1.4.3	Total number of approved registered products on contract basis could not be confirmed. Complete details of products registered on contract basis shall be submitted.	Applicant has 07 approved sections and applicant has also submitted that they no product is registered on contract manufacturing.
2	1.5.6	Official monograph is available in USP. Firm has claimed innovator's specifications in "1.5.6" section of form 5F.	Firm has provided new Form 5F wherein they have revised their specifications from innovator's specifications to USP specifications without submission of applicable fee.
3	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	Valid GMP certificate of API manufacturer is provided. Valid till 25-06-2023.
4	3.2. S.4	• Results of analysis of relevant batch(es) of drug substance performed by drug product manufacturer used during product development and stability studies along with COA of the same batch from drug substance/Active Pharmaceutical ingredient manufacturer. • Detailed analytical procedure for the drug substance by the drug product manufacturer shall be provided. • Analytical method verification studies including specificity, accuracy and repeatability (method precision) for drug substance performed by the drug product manufacturer shall be submitted.	Batch No. A-439 has been manufactured by API lot No. KM-0100918 while COA has only been submitted for API Lot No. KTM-180015 Submitted. Firm has submitted analytical method verification studies but chromatograms for finished product has been submitted.
5	3.2. P.8.3	ADC attested invoices of the drug substance used during product development and stability studies shall be submitted.	ADC attested invoice for API Lot No. KM-0100918 used in Batch No. A-439 has not been provided by the firm.
6	3.2. P.2.3	Justification of not performing terminal sterilization of the drug product.	Firm has submitted that we cannot perform terminal sterilization of ketorolac injection because it is heat sensitive product. Melting point of the API mentioned in DMF is 165-170 ºC.

7	3.2. P.5.2	Detailed analytical procedure for the drug product by the drug product manufacturer shall be provided.	Submitted.
8	3.2. P.5.3	In process validation protocol 30.45mg of ketorolac tromethamine is used. Justification is required whether overage or potency adjustment.	Firm has submitted that it is potency adjustment. The potency as per COA of drug substance on as is basis is 98.5%. On the basis of as is potency the quantity of powder to be dispensed is calculated as 30.45mg {(100/98.5) x 30 = 30.45}
9	3.2. P.8.3	Submit raw data sheets for stability studies, reflecting the details of Standard weight, Sample dilution preparation, Potency of Reference standard and Calculation formula applied for the Assay test.	Submitted.

Decision of 313th meeting of the Registration Board: Deferred for following;

- Submission of documents/commercial invoice for the procurement of API Lot No. KM-0100918 with approval from DRAP.
- Submission of scientific justification for not performing terminal sterilization of the drug product.
- Submission of 7500/- fee for revision of finished product specifications as per notification No. F. 7-11/2021-B&A/DRAP dated 13-07-2021.

Submission by the firm;

Sr. No.	Reason for deferment.	Submission/Justification by the firm.
1.	Submission of documents/commercial invoice for the procurement of API Lot No. KM-0100918 with approval from DRAP.	Firm has submitted clearance certificate attested by AD - I&E, DRAP, Islamabad dated 27-04-2018 for the ketorolac tromethamine B# KM-0100918.
2.	Submission of scientific justification for not performing terminal sterilization of the drug product.	Firm has submitted that we were not performing terminal sterilization earlier but now we started terminal sterilization. They have also attached review document.
3.	Submission of 7500/- fee for revision of finished product specifications as per notification No. F. 7-11/2021-B&A/DRAP dated 13-07-2021.	Firm has submitted fee of 7500/- vide slip No. 31868295920 dated 06-01-2022 for revision of specifications.

Decision of 316th meeting of the Registration Board: Deferred for scientific rationale of performing terminal sterilization, with reference to the innovator product.

Submission by the firm;

Firm has submitted a document with title of "ketorolac tromethamine injection- Google patents" wherein they have provided details of a product of a Chinese pharmaceutical i.e. Tianjin Chase Sun Pharmaceutical Co. Ltd. The document discloses a prescription of ketorolac tromethamine injection and preparation method. The invention can not only effectively solve the problem that the existing ketorolac tromethamine injection containing ethanol causes irritation while being injected and improve the safety of the drugs and compliance of the drugs but also completely avoid the white points caused by the traditional technology after sterilization treatment, and thus the ketorolac tromethamine injection is good in stability, high in safety, reliable in quality and significant in efficacy.

The document has also shown that the said injection is terminally sterilized.

Remarks of the Evaluator [XIII]

In actives mentioned in the formulation of the above said document has no Ethyl alcohol, while the applied formulation has followed the innovator product which contain ethyl alcohol as solvent which makes the difference between the two formulations.

Furthermore, the document provided by the firm is not from RRA.

Decision: Registration Board deferred the case for further deliberation regarding the sterilization method of the applied formulation whether by way of terminal sterilization or otherwise.

DRAP Authority in its 129th meeting held on 17-02-2022 decided as follows:

The Authority appreciated the efforts of PE&R Division for effective and phase wise implementation of CTD and after detailed deliberations approved the out of queue consideration of registration applications of New Chemical Entities on CTD format (Form 5F).

Accordingly, the following application is evaluated and placed before the Registration Board for consideration.

432.	Name, address of Applicant / Importer	Biocare Pharmaceutica, 807-Shadman 1, Lahore-Pakistan.
	Details of Drug Sale License of importer	DSL NO. 05-352-0063-032069D. Address: M/s Biocare Pharmaceutica, 807-Shadman 1, District Lahore. Go-down address: 8-C, Street No.3, Near LGS School, Shah Jamal, District Lahore. Valid up to 17-04-2022.
	Name and address of marketing authorization holder (abroad)	Wanbang Biopharmaceuticals. Manufacturing site Address: South of Dongshan, Comprehensive area, Jinshanqiao Development Zone, Xuzhou, Jiangsu China.
	Name, address of manufacturer(s)	Manufactured By: - Wanbang Biopharmaceuticals Manufacturing site Address: South of Dongshan, Comprehensive area, Jinshanqiao Development Zone, Xuzhou, Jiangsu China.
	Name of exporting country	China.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Detail of certificates attached (CoPP, GMP certificate) • Original legalized CoPP (certificate No. JS20210074) issued by Jiangsu Drug Administration, China on 20-01-2021. The document also confirms that the applied product strength is actually on the market in exporting country. Valid up to 19-01-2022. • Original legalized GMP certificate No. JS20180837 valid till 21/06/2023 issued by China Food and Drug Administration is submitted.
	Details of letter of authorization / sole agency agreement	Copy of product specific sole agency agreement is submitted.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 25527: dated 14-09-2021.
	Details of fee submitted	PKR 75,000/-: dated 04-08-2021.
	The proposed proprietary name / brand name	PARIX, Bio-P, Dynastat 40mg Powder for injection (IV/IM).
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 42.3 mg of parecoxib sodium equivalent to parecoxib …… 40mg.
	Pharmaceutical form of applied drug	(Parecoxib Sodium) 40 Mg (IM/IV) freez-dried Powder for Solution for Injection.

	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Antirheumatic products, Non-steroids (Coxibs). ATC code: M01AH04. ***For the short-term treatment of postoperative pain in adults.***
	Reference to Finished product specifications	In House specifications.
	Proposed Pack size	10 vials/carton, 50 cartons/box.
	Proposed unit price	PKR 500/vial.
	The status in reference regulatory authorities	DYNASTAT Injection contains 40 mg parecoxib (as 42.36 mg parecoxib sodium), TGA approved.
	For generic drugs (me-too status)	Could not be confirmed.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacturer, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Name, address of drug substance manufacturer	M/s Zhejiang Haisen Pharmaceutical Co. Ltd., Xiangtan Village, Liushi Street, Dongyang, City Zhejiang Province, China. Validity 24-09-2025.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 36 months real time stability data at 30°± 2°C / 65% RH ± 5% RH of 03 batches (5316110201, 5316110202, 5316120201). • 06 month accelerated stability data 40°C ± 2°C / 75% RH ± 5% RH of 03 batches (5316110201, 5316110202, 5316120201).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against reference product i.e. Dynastat 40mg powder for solution for injection, Batch No. R42343 with Exp. Date of 04/2019

		manufactured by the Pfizer Limited by performing the following tests; Appearance, Identification, pH, Clarity of solution, related compounds, water content, weight variation, particulate matter, sterility, bacterial endotoxin, visible particulates and Assay.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	5ml type I clear glass tubular injection vial with brominated butyl rubber stopper sealed with a blue flip-off cap on the aluminum seal.
	Stability study data of drug product, shelf life and storage conditions	• 12 months real time stability data at 30°C ± 2°C / 65% ± 5% RH of 03 batches (42001403, 42001404, 42001407). • 06 month accelerated stability data 40°C ± 2°C / 75% ± 5% RH of 03 batches (42001403, 42001404, 42001407). Finished product manufacturer has also submitted a commitment letter wherein they commit/confirm that complete full 24 month till shelf life Zone IVA stability study under 30°C ± 2°C / 65% ± 5% RH condition for their product Parecoxib 40mg powder for injection. They further submitted that they will update 15, 18 & 24-month time point stability data under Zone IVA conditions accordingly as soon as it is completed & tested.

Evaluation by PEC:

Sr. No.	Observations	Reply by the firm.
1	Notarized agreement shall be submitted.	Firm has again submitted copy of agreement.
2	Valid copy of DSL as the DSL is valid up to 17-04-2022.	Firm has provided provisional receipt of "Application for change in drug sale license 352-98572912-2022" with reference No. 352-98572912-2022 of M/s Biocare Pharmaceutica, 807 Shadman-1, District Lahore.
3	Valid CoPP shall be submitted. 19-01-2022.	Firm has submitted copy of CoPP (certificate No. JS20220091) issued by Jiangsu Drug Administration, China on 04-03-2022. The document also confirms that the applied product strength is actually on the market in exporting country. Valid up to 03-03-2023. ***Not notarized and countersigned by the embassy of Pakistan.***
4	Complete shelf life stability data of the applied formulation shall be submitted.	Firm has submitted 24-month real time stability data at 30°C ± 2°C / 65% ± 5% RH of three batches (42001403, 42001404, 42001407) for the applied formulation and results are within the limits.

Decision of 317th meeting of Registration Board:
Registration Board after thorough deliberation decided to deferred the case for further incorporations of complete details including approval status of the of the new chemical entity in reference regulatory authorities, indications, warnings etc.

Submission by the firm;

- **Firm has submitted valid, notarized and embassy of Pakistan countersigned CoPP valid till 03-03-2023.**
- **Firm has further submitted that the applied formulation is approved in the following reference regulatory authorities;**

a. Dynastat 40 mg powder for solution for injection of M/s Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom, MHRA approved.

Indication; For the short-term treatment of postoperative pain in adults.

Special warnings and precautions for use;

Dynastat has been studied in dental, orthopaedic, gynaecologic (principally hysterectomy) and coronary artery bypass graft surgery. There is limited experience in other types of surgery, for example gastrointestinal or urological surgery.

Modes of administration other than IV or IM (e.g. intra-articular, intrathecal) have not been studied and should not be used.

Because of the possibility for increased adverse reactions at higher doses of parecoxib, other COX-2 inhibitors and NSAIDs, patients treated with parecoxib should be reviewed following dose increase and, in the absence of an increase in efficacy, other therapeutic options should be considered (see section 4.2). There is limited clinical experience with Dynastat treatment beyond three days.

If, during treatment, patients deteriorate in any of the organ system functions described below, appropriate measures should be taken and discontinuation of parecoxib therapy should be considered.

Cardiovascular; COX-2 inhibitors have been associated with increased risk of cardiovascular and thrombotic adverse events when taken long term. The exact magnitude of the risk associated with a single dose has not been determined, nor has the exact duration of therapy associated with increased risk. Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with parecoxib after careful consideration (see section 5.1). Appropriate measures should be taken and discontinuation of parecoxib therapy should be considered if there is clinical evidence of deterioration in the condition of specific clinical symptoms in these patients. Dynastat has not been studied in cardiovascular revascularization procedures other than coronary artery bypass graft (CABG) procedures. Studies in types of surgery other than CABG procedures included patients with American Society of Anaesthesiology (ASA) Physical Status Class I-III only.

Acetylsalicyclic acid and other NSAIDs; COX-2 inhibitors are not a substitute for acetylsalicylic acid for prophylaxis of cardiovascular thrombo-embolic diseases because of their lack of antiplatelet effects. Therefore, antiplatelet therapies should not be discontinued (see section 5.1). Caution should be exercised when coadministering Dynastat with warfarin and other oral anticoagulants (see section 4.5). The concomitant use of parecoxib with other non- acetylsalicylic acid NSAIDs should be avoided. Dynastat may mask fever and other signs of inflammation (see section 5.1). In isolated cases, an aggravation of soft tissue infections has been described in connection with the use of NSAIDs and in nonclinical studies with Dynastat (see section 5.3). Caution should be exercised with respect to monitoring the incision for signs of infection in surgical patients receiving Dynastat.

Gastrointestinal; Upper gastrointestinal (GI) complications (perforations, ulcers or bleedings [PUBs]), some of them resulting in fatal outcome, have occurred in patients treated with parecoxib. Caution is advised in the treatment of patients most at risk of developing a gastrointestinal complication with NSAIDs; the elderly, or patients with a prior history of gastrointestinal disease, such as ulceration and GI bleeding, or patients using acetylsalicylic acid concomitantly. The NSAIDs class is also associated with increased GI complications when coadministered with glucocorticoids, selective serotonin reuptake inhibitors, other antiplatelet drugs, other NSAIDs or patients ingesting alcohol. There is further increase in the risk of gastrointestinal adverse effects (gastrointestinal ulceration or other gastrointestinal complications), when parecoxib is taken concomitantly with acetylsalicylic acid (even at low doses).

Skin reactions; Serious skin reactions, including erythema multiforme, exfoliative dermatitis and Stevens-Johnson syndrome (some of them fatal) have been reported through post-marketing surveillance in patients receiving parecoxib. Additionally, fatal reports of toxic epidermal necrolysis have been reported through postmarketing surveillance in patients receiving valdecoxib (the active metabolite of parecoxib) and cannot be ruled out for parecoxib (see section 4.8). DRESS syndrome may occur with parecoxib exposure based on other serious skin reactions reported with celecoxib and valdecoxib exposure. Patients appear to be at highest risk for these reactions early in the course of therapy; the onset of the reaction occurring in the majority of cases within the first month of treatment. Appropriate measures should be taken by physicians to monitor for any serious skin reactions with therapy, e.g. additional patient consultations. Patients should be advised to immediately report any emergent skin condition to their physician. Parecoxib should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. Serious skin reactions are known to occur with NSAIDs including COX-2 selective inhibitors as well as other medicinal products. However, the reported rate of serious skin events appears to be greater for valdecoxib (the active metabolite of parecoxib) as compared to other COX-2 selective inhibitors. Patients with a history of sulfonamide allergy may be at greater risk of skin reactions (see section 4.3). Patients without a history of sulfonamide allergy may also be at risk for serious skin reactions.

Hypersensitivity; Hypersensitivity reactions (anaphylaxis and angioedema) have been reported in post-marketing experience with valdecoxib and parecoxib (see section 4.8). Some of these reactions have occurred in patients with a history of allergictype reactions to sulfonamides (see section 4.3). Parecoxib should be discontinued at the first sign of hypersensitivity. Cases of severe hypotension shortly following parecoxib administration have been reported in postmarketing experience with parecoxib. Some of these

cases have occurred without other signs of anaphylaxis. The physician should be prepared to treat severe hypotension.

Fluid retention, oedema, renal; As with other medicinal products known to inhibit prostaglandin synthesis, fluid retention and oedema have been observed in some patients taking parecoxib. Therefore, parecoxib should be used with caution in patients with compromised cardiac function, preexisting oedema, or other conditions predisposing to, or worsened by, fluid retention including those taking diuretic treatment or otherwise at risk of hypovolemia. If there is clinical evidence of deterioration in the condition of these patients, appropriate measures including discontinuation of parecoxib should be taken. Acute renal failure has been reported through post-marketing surveillance in patients receiving parecoxib (see section 4.8). Since prostaglandin synthesis inhibition may result in deterioration of renal function and fluid retention, caution should be observed when administering Dynastat in patients with impaired renal function (see section 4.2) or hypertension, or in patients with compromised cardiac or hepatic function or other conditions predisposing to fluid retention. Caution should be used when initiating treatment with Dynastat in patients with dehydration. In this case, it is advisable to rehydrate patients first and then start therapy with Dynastat.

Hypertension; As with all NSAIDs, parecoxib can lead to the onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of cardiovascular events. Parecoxib should be used with caution in patients with hypertension. Blood pressure should be monitored closely during the initiation of therapy with parecoxib and throughout the course of therapy. If blood pressure rises significantly, alternative treatment should be considered.

Hepatic impairment; Dynastat should be used with caution in patients with moderate hepatic impairment (Child-Pugh score 7-9).

Use with oral anticoagulants; The concomitant use of NSAIDs with oral anticoagulants increases the risk of bleeding. Oral anticoagulants include warfarin/coumarin-type and novel oral anticoagulants (e.g. apixaban, dabigatran, and rivaroxaban).

Sodium content; This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

Contraindications;

Hypersensitivity to the active substance or to any of the excipients.

History of previous serious allergic drug reaction of any type, especially cutaneous reactions such as Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms syndrome (DRESS syndrome), toxic epidermal necrolysis, erythema multiforme or patients with known hypersensitivity to sulfonamides.

Active peptic ulceration or gastrointestinal (GI) bleeding.

Patients who have experienced bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema, urticaria or other allergic-type reactions after taking acetylsalicylic acid or nonsteroidal anti-inflammatory drugs (NSAIDs) including COX-2 inhibitors.

The third trimester of pregnancy and breast-feeding.

Severe hepatic impairment (serum albumin < 25g/l or child-pugh score is ≥ 10).

Inflammatory bowel disease.

Congestive heart failure (NYHA II-IV).

Treatment of post-operative pain following coronary artery bypass graft (CABG) surgery.

Established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

b. Dynastat 40 mg powder for solution for injection of M/s Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium, EMA approved.

c. DYNASTAT parecoxib (as sodium) 40mg powder for injection vial, Pfizer Australia Pty Ltd., TGA Australia approved.

Decision: Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Registration applications of Veterinary drugs on Form 5.

433.	Name and address of manufacturer/ Applicant	M/s Nawan Laboratories (Pvt.) Ltd., plots No. 136, sector 15, Korangi Industrial Area Karachi (Dry powder sachet section (General) veterinary).
	Brand Name + Dosage Form + Strength	Easy Digest powder.
	Composition	Each 1000gm contains: Propionic Acid Calcium ……..250gm

		Propionic Acid Sodium ……400gm Acetanilide ……150gm Magnesium Oxide ……125gm Iron II Sulphate ……..0.400mg Zinc Sulphate ……0.100mg Magnesium Sulphate ……...0.200mg Copper Sulphate ……..0.450mg Cobalt Sulphate ……0.400mg Sodium Molybdate ……0.100mg Sodium Chloride ……20gm
	Diary No. Date of R & I & fee	Dy. No 11444 dated 05-03-2019; Rs.20,000/- dated 04-03-2019.
	Pharmacological Group	Appetizing and digestive tonic powder.
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications.
	Pack size & Demanded Price	100gm sachet & decontrolled.
	Approval status of product in Reference Regulatory Authorities	N/A.
	Me-too status	Alvegest powder, Star Laboratories, Reg. No. 008029.
	GMP status	Firm has submitted routine GMP inspection report dated 25-01-2022 wherein it is concluded that keeping in view the attitude of the management towards continuous improvements and current observations their overall GMP compliance is rated as good.
	Remarks of the Evaluator	• Firm was asked to revise their label claim as per their demanded pack size. They revised their label claim as follows; Each 100-gm powder contains; Propionic Acid Calcium ……..25gm Propionic Acid Sodium ……40gm Acetanilide ……15gm Magnesium Oxide ……12.5gm Iron II Sulphate ……0.040mg Zinc Sulphate ……0.010mg Magnesium Sulphate ……0.020mg Copper Sulphate ……...0.045mg Cobalt Sulphate ……0.040mg Sodium Molybdate ……0.010mg Sodium Chloride ……2gm • Firm has submitted me too details as Alvegest powder manufactured by Star Laboratories, Reg. No. 008029. • ***However, the composition of the applied formulation is different from the already approved formulation.***
	Decision: Deferred for submission evidence of already approved formulation by the Registration Board with brand name, Registration number & manufacturer name. As the composition of the applied formulation is different from submitted me too in concentration of Iron II Sulphate, Zinc, Magnesium Sulphate, Copper Sulphate, Cobalt Sulphate and Sodium Molybdate.	

Registration applications of deferred Veterinary drugs on Form 5.

434.	Name and address of manufacturer/ Applicant	M/s Attabak Pharmaceutical Industries, 5-C Industrial Area, I- 10/3 Islamabad
	Brand Name + Dosage Form + Strength	TRICLOSOLE Bolus
	Composition	Each Bolus contains Triclabendazole ……900mg Levamisole ……90mg
	Diary No. Date of R & I & fee	Dy. No. 13832, Dated: 24/05/2021, Rs. 30,000/-
	Pharmacological Group	Anthelmintic

	Type of Form	Form-5
	Finished product Specification	As Per Innovator's Specification
	Pack size & Demanded Price	4 x5'S, 10 x5'S & 20 x5'S
	Me-too status	Tribazole Plus Bolus 900mg/90mg (R# 074039) Selemore pharmaceuticals Pvt Ltd
	GMP status	Panel inspection conducted on 08-02-2021 for renewal of DML & grant of Additional Sections. Panel recommended grant of Additional Sections.
	Remarks of the Evaluator	
	Previous decision **(M-312)**	Deferred for correction of the salt form of Levamisole in label claim along with submission of applicable fee.
	Evaluation by PEC	Firm has submitted that: *Our applied composition is already as per me-too applied.'* However, As per Product Information Database of Veterinary Medicines Directorate, MHRA Levamisole is approved as Levamisole hydrochloride for oral dosage form.
	Previous decision **(M-316)**	Deferred for correction of the salt form of Levamisole in label claim along with submission of applicable fee.
	Submission by the firm.	Firm has submitted their revised formulation as per decision of 316 meeting of the Registration Board with submission of fee of 7500/- vide slip No. 71086384236 dated 22-06-2022. **Revised label claim is as under;** **Each Bolus contains** **Triclabendazole ……900mg** **Levamisole Hydrochloride……90mg**
	Remarks of the Evaluator [XIII]	However, firm has not revised the label claim as per Product Information Database of Veterinary Medicines Directorate, MHRA where Levamisole is approved as Levamisole hydrochloride while the firm has applied Levamisole hydrochloride. Furthermore, for change of salt form full fee shall be submitted.
	Decision: Approved with innovator's specifications. • **Registration Board further decided that registration letter will be issued upon submission of revised label claim as per innovator product declaring the salt form of Levamisole as Levamisole HCl, submission of full fee for correction/pre-approval change in salt form of drug substance, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

Registration applications of deferred Human drugs on Form 5.

435.	Name and address of manufacturer/ Applicant	M/s Fedro Pharmaceuticals Lab Pvt. Ltd, 149-Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	Keyfed tablet 1mg
	Composition	Each film- coated tablet contains: Ketotifen as Fumarate……1mg
	Diary No. Date of R & I & fee	Dy.No.27229; 08-08-2018; Rs.20,000 (08-08-2018)
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved as uncoated
	Me-too status	Asthanil 1mg Tab of M/s Siza Lahore (Reg. # 011751)
	GMP status	Last GMP inspection was conducted on 30-01-2019 and the report concludes:

		The firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance.
	Remarks of the Evaluator	• Initially, film- coated tablet was applied while it is approved in Italy (AIFA) as uncoated. • Firm has revised its master formulation according to the reference and has submitted Rs. 5000/- for change of formulation. • The applied formulation is non- pharmacopoeial. • General tablet section is available in the firm as mentioned in the submitted GMP certificate. • Applied salt is not complete because Ketotifen as "Hydrogen" fumarate is approved in MHRA. Firm did not correct the salt in reply.
	Decision of 293rd meeting of Registration Board.	Deferred for revision of formulation as per reference product along with submission of requisite fee.
	Submission by the firm.	Firm has submitted that in response to letter No. F.1-1/2017/PEC-DRAP (AD PEC XIII), they have already submitted 5000/- fee while their product is still pending.
	Remarks of the Evaluator XIII	• Firm has neither submitted revised label claim as per reference product nor any fee for revision of label claim against the decision of 293rd meeting of Registration Board. • Latest GMP certificate/inspection report conducted within last three years shall be submitted.
	Decision: Approved with innovator's specifications as per following label claim: "Each tablet contains: Ketotifen as Fumarate …… 1mg" • **Registration letter will be issued after submission of differential fee of Rs. 2,500 for correction/pre-approval change in dosage from film coated to uncoated tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Firm will also submit latest GMP certificate/last inspection report conducted within last three years.**	
436.	Name and address of manufacturer/ Applicant	M/s Scilife Pharma Pvt Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi. (Contract giver) M/s Vision Pharmaceuticals, Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad. (contract acceptor) (Large volume & small volume parenteral.)
	Brand Name + Dosage Form + Strength	Orpic 200mg/100ml IV Infusion.
	Composition	Each 100ml Contains: Ciprofloxacin Lactate eq. to Ciprofloxacin …200mg
	Diary No. Date of R & I & fee	Dy. No 16170 dated 07-03-2019; Rs.50,000/- dated 07-03-2019.
	Pharmacological Group	Quinolone Antibacterial.
	Type of Form	Form-5.
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	1 x 100ml & as per SRO.
	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin 2 mg/ml (As lactate) solution for infusion, MHRA approved.
	Me-too status	Otsuflox IV Infusion 100ml, Otsuka Pakistan, Reg. No. 086880.
	GMP status	Vision Pharma: GMP certificate issued on 31-07-2019 on the basis of inspection conducted on 11-02-2019. Scilife pharma:

		GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator	• Packaging material of the applied formulation is LDPE and is different from the reference product which is PVC bag contained in a polypropylene/polyester aluminum/polyester pouch. • Master formula has ciprofloxacin lactate and lactic acid while BP monograph states that ciprofloxacin infusion is a sterile solution prepared by the interaction of ciprofloxacin and lactic acid. • M/s Scilife Pharma has 06 approved sections vide letter No. F. 2-4/2011-Lic (Vol-I) dated 18-06-2021. • M/s Scilife Pharma has also submitted that they have 09 approved products on contract basis.
	Decision of 312th meeting of Registration Board.	Deferred for following: • Packaging material of the applied formulation is LDPE and is different from the reference product which is PVC bag contained in a polypropylene/polyester aluminium/polyester pouch. • Master formula has ciprofloxacin lactate and lactic acid while BP monograph states that ciprofloxacin infusion is a sterile solution prepared by the interaction of ciprofloxacin and lactic acid. Master formulation needs revision along with submission of application of applicable fee.
	Submission by the firm.	• Firm has submitted that according to innovator manufactured by Hospira UK Ltd., ciprofloxacin solution for infusion supplied in transparent infusion bags (PVC or Polyolefin). We are mentioning LDPE, which belongs to polyolefin. Furthermore, we also performed the stability of product in LDPE which shows that the product is compatible with LDPE container. • Firm has also submitted that we have manufactured our product according the innovator product while lactic acid 50% is mentioned in list of excipients. Lactic acid is added as an acidifying agent to improve the solubility of API. Thus, there will be no revision in formulation.
	Remarks of the Evaluator [XIII]	• BP monograph states that ciprofloxacin infusion is a sterile solution prepared by the interaction of ciprofloxacin and lactic acid.
	Decision: Deferred for following points: • **Revision of formulation as per BP monograph along with submission of full fee.** • **Details regarding formulation and salt form of ciprofloxacin along with current status of the commercial product manufactured by M/s vision pharmaceuticals.**	
437.	Name and address of manufacturer/ Applicant	M/s Scilife Pharma Pvt Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi. (Contract giver) M/s Vision Pharmaceuticals, Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad. (contract acceptor) (Large volume & small volume parenteral.)
	Brand Name + Dosage Form + Strength	Scimox 400mg/250ml IV Infusion.

	Composition	Each 250ml Contains: Moxifloxacin HCL eq. to Moxifloxacin ……400mg
	Diary No. Date of R & I & fee	Dy. No 16169 dated 07-03-2019; Rs.50,000/- dated 07-03-2019.
	Pharmacological Group	Quinolone Antibacterial.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer's specifications.
	Pack size & Demanded Price	1 x 250ml & as per SRO.
	Approval status of product in Reference Regulatory Authorities	Avelox 400 mg/250 ml solution for infusion, MHRA approved.
	Me-too status	Zeker 400mg/250ml Infusion, ISIS Pharmaceutical, Reg. No. 092704.
	GMP status	Vision Pharma: GMP certificate issued on 31-07-2019 on the basis of inspection conducted on 11-02-2019. Scilife pharma: GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator	• Packaging material of the applied formulation is LDPE and is different from the reference product which is PVC bag contained in a polypropylene/polyester aluminum/polyester pouch. • M/s Scilife Pharma has 06 approved sections vide letter No. F. 2-4/2011-Lic (Vol-I) dated 18-06-2021. • M/s Scilife Pharma has also submitted that they have 09 approved products on contract basis.
	Decision of 312th meeting of Registration Board.	Deferred for following: • Packaging material of the applied formulation is LDPE and is different from the reference product which is PVC bag contained in a polypropylene/polyester aluminium/polyester pouch.
	Submission by the firm.	• Firm has submitted that according to innovator Avelox 400mg/250ml solution for infusion, Moxifloxacin solution for infusion supplied in polyolefin bags. We are mentioning LDPE, which belongs to class polyolefin. Furthermore, we also performed the stability of product in LDPE which shows that the product is compatible with LDPE container.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
438.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals (Pvt.) Ltd., Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Mefalgic 50mg/5ml Suspension
	Composition	Each 5ml contains: Mefenamic Acid ……50mg
	Diary No. Date of R & I & fee	Dy. No 5328 dated 07-02-2019 Rs.20,000/-06-02-2019
	Pharmacological Group	Anti-inflammatory and Antirheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 450ml: As per SSRO

	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Constel 50mg/5ml suspension
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator PEC	• Mention type of primary packaging material • Approval status of product in reference regulatory authorities?
	Decision of 296th meeting of Registration Board. :	Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Mention type of primary packaging material for applied formulation.
	Submission by the firm.	Firm has submitted PIL of mefenamic acid 50mg/5ml suspension approved by Netherland. However, the same could not be confirmed. Firm has also submitted the art work of applied formulation instead of primary packaging material.
	Remarks of Evaluator PEC-XIII.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Mention type of primary packaging material for applied formulation.
	Decision of 307th meeting of Registration Board. :	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Mention type of primary packaging material for applied formulation.
	Submission by the firm.	Firm has submitted an evidence for the applied formulation approved in MHRA. Mefenamic Acid 50 mg/5 ml Suspension, Marketing Authorization holder is Chemidex Pharma Limited and marketing Authorization number is PL 17736/0146.
	Remarks of Evaluator PEC XIII.	• Type of primary packaging material for applied formulation could not be confirmed. • Latest GMP status of the firm could not be confirmed.
	Decision: Approved with innovator's specifications. • **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Firm will also submit details of primary packaging material and current GMP status of the manufacturing site.**	
439.	Name and address of manufacturer/ Applicant	M/s Hi-Med Pharmaceuticals, (Pvt.) Ltd., 208-C Sunder Industrial Estate (P.I.E), Raiwind Road, Lahore (Tablet general).
	Brand Name + Dosage Form + Strength	Medigex 100mg Tablet.
	Composition	Each Film Coated Tablet Contains: Sertraline HCl……..100mg
	Diary No. Date of R & I & fee	Dy. No 9939 dated 04-03-2019; Rs.20,000/- 28-02-2019
	Pharmacological Group	SSRI

	Type of Form	Form-5.
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	20's & as per SRO.
	Approval status of product in Reference Regulatory Authorities	ZOLOFT (sertraline hydrochloride), USFDA approved.
	Me-too status	Lintre Tab 100mg, Indus Pharma, Reg. No. 048481
	GMP status	GMP status of the firm could not be confirmed.
	Remarks of the Evaluator PEC-XIII.	Firm submitted panel inspection report for grant of new drug manufacturing license conducted on 27-04-2018 wherein the panel recommended the grant of DML by the way of formulation to M/s Hi-Med Pharmaceuticals.
	Decision of 307th meeting of Registration Board. :	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 102/2022-DRAP(AD-37320885037) dated 27-06-2022 issued on the basis of inspection conducted on 10-06-2022.
	Remarks of Evaluator PEC XIII.	
	Decision: Approved.	
440.	Name and address of manufacturer/ Applicant	M/s Hi-Med Pharmaceuticals, (Pvt.) Ltd., 208-C Sunder Industrial Estate (P.I.E), Raiwind Road, Lahore (Tablet general).
	Brand Name + Dosage Form + Strength	Citamed Plus 50mg/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin phosphate monohydrate Eq. to Sitagliptin……..…50mg Metformin HCL……..1000mg
	Diary No. Date of R & I & fee	Dy. No 9945 dated 04-03-2019; Rs.20,000/- 28-02-2019
	Pharmacological Group	Anti-Diabetic
	Type of Form	Form-5.
	Finished product Specification	Manufacturer's Specification.
	Pack size & Demanded Price	14's & as per SRO.
	Approval status of product in Reference Regulatory Authorities	Janumet 50/1000mg tablets (USFDA approved)
	Me-too status	Duvel plus 50/1000mg tablets, Martin Dow, reg. no. 075895.
	GMP status	GMP status of the firm could not be confirmed.
	Remarks of the Evaluator PEC-XIII.	Firm submitted panel inspection report for grant of new drug manufacturing license conducted on 27-04-2018 wherein the panel recommended the grant of DML by the way of formulation to M/s Hi-Med Pharmaceuticals.
	Decision of 307th meeting of Registration Board. :	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 102/2022-DRAP(AD-37320885037) dated 27-06-2022 issued on the basis of inspection conducted on 10-06-2022.
	Remarks of Evaluator PEC XIII.	
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
441.	Name and address of manufacturer/ Applicant	M/s Hi-Med Pharmaceuticals, (Pvt.) Ltd., 208-C Sunder Industrial Estate (P.I.E), Raiwind Road, Lahore (Tablet general).
	Brand Name + Dosage Form + Strength	Medopa 250mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Methyldopa eq to anhydrous methyldopa…250mg
	Diary No. Date of R & I & fee	Dy. No 9951 dated 04-03-2019; Rs.20,000/- 28-02-2019
	Pharmacological Group	Anti-hypertensive.
	Type of Form	Form-5.
	Finished product Specification	BP Specification.
	Pack size & Demanded Price	100's & as per SRO.
	Approval status of product in Reference Regulatory Authorities	Methyldopa 250mg Tablets, Nexcape Pharmaceuticals Ltd., MHRA approved.
	Me-too status	Aldomet tablets, MSD, Karachi, Reg. No. 000311.
	GMP status	GMP status of the firm could not be confirmed.
	Remarks of the Evaluator PEC-XIII.	Firm submitted panel inspection report for grant of new drug manufacturing license conducted on 27-04-2018 wherein the panel recommended the grant of DML by the way of formulation to M/s Hi-Med Pharmaceuticals.
	Decision of 307th meeting of Registration Board. :	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 102/2022-DRAP(AD-37320885037) dated 27-06-2022 issued on the basis of inspection conducted on 10-06-2022.
	Remarks of Evaluator PEC XIII.	
	Decision: Approved.	
442.	Name and address of manufacturer/ Applicant	M/s Hi-Med Pharmaceuticals, (Pvt.) Ltd., 208-C Sunder Industrial Estate (P.I.E), Raiwind Road, Lahore (Tablet general).
	Brand Name + Dosage Form + Strength	Pentomed 40mg Tablets.
	Composition	Each enteric coated tablet contains: Pantoprazole as sodium sesquihydrate …..40mg
	Diary No. Date of R & I & fee	Dy. No 9934 dated 04-03-2019; Rs.20,000/- 28-02-2019
	Pharmacological Group	Proton Pump Inhibitor (PPI's)
	Type of Form	Form-5.
	Finished product Specification	USP Specification.
	Pack size & Demanded Price	10's, 14's & as per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved.
	Me-too status	Pantberg 40mg Enteric Coated Tablets, Ice Berg Pharmaceuticals, Reg. No. 079782.
	GMP status	GMP status of the firm could not be confirmed.
	Remarks of the Evaluator PEC-XIII.	Firm submitted panel inspection report for grant of new drug manufacturing license conducted on 27-04-2018 wherein the panel recommended the grant of DML by the way of formulation to M/s Hi-Med Pharmaceuticals.
	Decision of 307th meeting of Registration Board. :	Deferred for updated status of GMP of the firm from QA & LT Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 102/2022-DRAP(AD-37320885037) dated 27-06-2022 issued on the basis of inspection conducted on 10-06-2022.
	Remarks of Evaluator PEC XIII.	
	Decision: Approved.	

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443.	Name and address of manufacturer / Applicant	M/s. Medisearch Pharmacal Private Limited 51-Km Raiwind Manga Road, Lahore Contract manufacturing from M/s. Friend Pharma (Pvt.) Ltd. 31-Km Ferozpur Road, Lahore
	Brand Name +Dosage Form + Strength	Levocin 500mg Infusion
	Composition	Each 100ml contains: Levofloxacin……..500mg
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No. dated 27-07-2009 Rs.8,000/- (Photocopy) Differential fee (Photocopy) of Rs.42,000/- submitted on Dy. No. dated 29-04-2013
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per S.R. O
	Approval status of product in Reference Regulatory Authorities	Levofloxacin Ibigen 5 mg/ml solution for infusion (100ml vial) by M/s Ibigen, MHRA Approved.
	Me-too status (with strength and dosage form)	Levosafe 500mg/100ml Infusion by M/s safe Pharma, Reg. no. 048882
	GMP status	M/s Medisearch Pharmacal: The firm is granted GMP certificate based on inspection conducted on 22-02-2021. M/s Friends Pharma: The firm is granted GMP certificate based on inspection conducted on 27-03-2019. Following sections of M/s Friends pharma are mentioned on said certificate: Capsule, tablet, cream/ointment, oral dry powder suspension, Liquid Injection, Dry powder injection and dry powder for injection (Lyophilized)
	Remarks of the Evaluator	• Firm provide the details of products already on contract manufacturing. (3 products are on contract manufacturing) • Section approval letter of LVP • Firm applied for levofloxacin…500mg/100ml while the reference product is levofloxacin as hemihydrate. 5 mg/ml solution for infusion (100ml vial). So, correction/revision of formulation is required accordingly. • Firm applied for BP specification while the official monograph of applied formulation is not present in BP. • Firm applied for revision of formulation as per reference i.e., Each vial of 100ml contains: Levofloxacin as hemihydrate….500mg without submission of the requisite fee. • Further requested to change the specification from BP to Manufacturer's specification. • Bacitrol Infusion (Moxifloxacin) 400mg/250ml (Reg.no.081273) and Nadosaline IV infusion

		(Normal Saline)100ml (Reg.no. 088794) are the two registered products of Friends Pharma which indicate firm has both LVP and SVP section.
	Previous Decision(s)	Deferred for revision of formulation considering the salt factor of active ingredient as per reference product i.e. Levofloxacin as hemihydrate…500mg/100ml along with requisite fee, revised master formulation and manufacturing method.
	Remarks of the Evaluator	The firm has revised the formulation alongwith master formulation and manufacturing outline as below: Each 100ml contains: Levofloxacin as hemihydrate……..500mg
	Decision: Approved with following label claim: **Each 100ml contains:** **Levofloxacin as hemihydrate……..500mg** • **Registration Board further decided that registration letter will be issued after submission of 75,000/- fee for revision of formulation as per innovator's product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
444.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal (Pvt.) Ltd., 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Medival Tablet 250mg
	Composition	Each Tablet contains: Divalproex Sodium……250mg
	Diary No. Date of R& I & fee	20-04-2011 vide diary No. 4616 Rs.8000 dated.31-07-2013 Rs.12,000/-
	Pharmacological Group	(Anticonvulsant)
	Type of Form	Form-5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA as delayed release tablet with the following box warning: WARNING: LIFE THREATENING ADVERSE REACTIONS See full prescribing information for complete boxed warning. • Hepatotoxicity, including fatalities, usually during the first 6 months of treatment. Children under the age of two years and patients with mitochondrial disorders are at higher risk.Monitor patients closely, and perform serum liver testing prior to therapy and at frequent intervals thereafter. • Fetal Risk, particularly neural tube defects, other major malformations, and decreased IQ • Pancreatitis, including fatal hemorrhagic cases
	Me-too status (with strength and dosage form)	Epival 250mg by M/s Abbott.
	GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Previous remarks of the Evaluator.	
	Previous Decision(s)	Deferred for revision of formulation as per the reference i.e. Each delayed-release tablet contains: divalproex sodium equivalent to valproic acid 500 mg along with submission of requisite fee, Form-5, master formulation and Manufacturing method (308).
	Evaluation by PEC	• Firm has submitted copy of differential fee challan details are given above.

		• Firm claimed BP Specification • Remaining documents as per the decision of previous meeting (M-256) has provided by the firm • Firm has revised the formulation from film coated to enteric coated tablet and accordingly change form-5, master formulation & manufacturing process without the requisite fee. Each delayed-release tablet contains: Divalproex sodium equivalent to valproic acid…….500 mg
	Remarks of the Evaluator	
	Decision: Approved with following label claim: **Each delayed-release tablet contains:** **Divalproex sodium equivalent to valproic acid…….500 mg** • **Registration Board further decided that registration letter will be issued after submission of 30,000/- fee for revision of formulation as per innovator's product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
445.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal (Pvt.) Ltd., 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Medicef Capsule 400mg
	Composition	Each capsule contains: Cefixime as trihydrate….....400mg
	Diary No. Date of R& I & fee	Form-5 Dy. No. 1312 dated. 20-12-2013 Rs. 20000/-
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer,s Spec,s
	Pack size & Demanded Price	AS Per SRO/10's
	Approval status of product in Reference Regulatory Authorities	USFDA Suprax (Lupin Ltd.)
	Me-too status (with strength and dosage form)	Cefiget (Getz Pharma Pakistan (Pvt.) Ltd.)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Previous remarks of the Evaluator.	The firm has provided Capsule (General & cephalosporin) section as mentioned in GMP certificate
	Previous decision(s) (M-307)	Registration Board deferred the case for further deliberation regarding finished product specifications of applied formulation/strength as product is not available in JP (M-307).
	Evaluation by PEC	The firm has submitted revised finished product specifications as manufacturer's specifications in accordance with DRAP letter no. F. 14-1/2022-PEC dated 14-03-2022.
	Remarks of the Evaluator	
	Decision: Approved with manufacturer's specifications in accordance with DRAP letter no. F. 14-1/2022-PEC dated 14-03-2022. • **Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
446.	Name and address of manufacturer / Applicant	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore-Gujranwala Road Khori District Sheikhupura
	Brand Name +Dosage Form + Strength	Calcium chloride Injection
	Composition	Each 10ml contains: Calcium chloride $2H_2O$…..……..2000mg

	Diary No. Date of R& I & fee	Dy. No 28768 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml x 10 Ampoules, 10ml x 5 Ampoules & As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	Calcium Chloride Injection of M/s LC&PW, Lahore
	GMP status	DML by way of formulation dated 02-12-2014 & GMP compliance inspection dated 21-02-2018
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting (M-292).
	Evaluation by PEC	The firm has submitted reference Baxter Healthcare corporation 15mg/100ml Calcium chloride : 1g /10ml ampoules Galenica MA (Italy)
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in 10ml fill volume in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

447.	Name and address of manufacturer / Applicant	M/s The Searle Company Limited, 32Km Multan Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Spingab capsule 225mg
	Composition	Each capsule contains: Pregabalin……225mg
	Diary No. Date of R& I & fee	Dy.No 2023, 03-04-2017, Rs.20,000/- 03-04-2017
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	2 x 7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved.
	Me-too status	Not available in the applied strengths (50,75,100,150,200 & 300 available)
	GMP status	GMP certificate issued on 13-08-2020 on the basis of inspection conducted on 11-07-2019.
	Previous remarks of the Evaluator.	Confirmed as 2ml, 10 ml and 20ml vial in MHRA, UK.
	Previous Decision	The product approved in 316th meeting of RB (M-316).
	Evaluation by PEC	Me-too reference of Nurica 225mg Capsule of M/s Macter international (Reg # 086889) has been verified. The firm has submitted that the said product has been approved with wrong manufacturing site. The correct manufacturing site is "M/s The Searle Company Limited, 32Km Multan Road, Lahore, Pakistan". It is requested to grant us registration as per the correct manufacturing site.
	Decision: Approved with Innovator's specifications. • **Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

<table>
<tr><td rowspan="14">448.</td><td>Name and address of manufacturer / Applicant</td><td>M/s The Searle Company Limited, F-319 SITE, Karachi, Pakistan</td></tr>
<tr><td>Brand Name +Dosage Form + Strength</td><td>HEMONSTIL 500mg/10ml INJECTION</td></tr>
<tr><td>Composition</td><td>Each 10ml injection contains:
Iron as Ferric carboxymaltose……500mg</td></tr>
<tr><td>Diary No. Date of R& I & fee</td><td>Diary No: 1793, 12-01-2018, Rs: 20,000/-, 11-01-2018</td></tr>
<tr><td>Pharmacological Group</td><td>Haematinic</td></tr>
<tr><td>Type of Form</td><td>Form-5</td></tr>
<tr><td>Finished product Specifications</td><td>Manufacturer’s specifications</td></tr>
<tr><td>Pack size & Demanded Price</td><td>1'sx10ml/As per SRO</td></tr>
<tr><td>Approval status of product in Reference Regulatory Authorities</td><td>Ferinject 50 mg iron/mL solution for injection/infusion. By M/s Vifor France (MHRA approved)</td></tr>
<tr><td>Me-too status</td><td>Ferinject 500mg/10ml by M/s RG. Pharmaceuticals (Reg#072548)</td></tr>
<tr><td>GMP status</td><td>The firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 11-07-2019.</td></tr>
<tr><td>Previous remarks of the Evaluator.</td><td>Confirmed as 2ml, 10 ml and 20ml vial in MHRA, UK.</td></tr>
<tr><td>Previous Decision</td><td>Registration Board deferred the case for comments regarding patent status of applied formulation from legal division (M-292).</td></tr>
<tr><td>Evaluation by PEC</td><td>The firm has submitted that recently multiple companies have been granted with product approval, details appended below:
<table>
<tr><th>Sr. No.</th><th>Applicant name</th><th>Product name</th><th>Approval</th></tr>
<tr><td>1.</td><td>Welmark pharma</td><td>Irofer 500mg /10ml</td><td>316 DRB</td></tr>
<tr><td>2.</td><td>CCL Pharma</td><td>Wirose inj. 50/ml</td><td>308 DRB</td></tr>
<tr><td>3.</td><td>Rotex Pharma</td><td>Ferriject 500mg/10ml inj</td><td>307 DRB</td></tr>
<tr><td>4.</td><td>Welwrd pharma</td><td>Faltose 50mg/ml Inj.</td><td>307 DRB</td></tr>
</table>
The firm has revised the label claim as below:
Each ampoule of 10ml contains:
Iron as ferric carboxymaltose…….500mg
Fee of PKR 30,000/- (slip number 159269612045) dated 03-08-2022 has been submitted.
The firm has provided liquid injectable (ampoule) section.</td></tr>
<tr><td colspan="2">Decision: Approved with Innovator’s specifications.
• Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.</td></tr>
<tr><td rowspan="8">449.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.</td></tr>
<tr><td>Brand Name +Dosage Form + Strength</td><td>Combifer Infusion 500mg/10ml</td></tr>
<tr><td>Composition</td><td>Each 10ml vial contains:
Iron carboxymaltose complex eq to Elemental Iron……500mg</td></tr>
<tr><td>Diary No. Date of R& I & fee</td><td>Diary No: 24080, 13-12-2017, Rs: 20,000/-</td></tr>
<tr><td>Pharmacological Group</td><td>Haematinic</td></tr>
<tr><td>Type of Form</td><td>Form-5</td></tr>
<tr><td>Finished product Specifications</td><td>Innovator’s specifications</td></tr>
<tr><td>Pack size & Demanded Price</td><td>1'sx10ml/As per SRO</td></tr>
</table>

	Approval status of product in Reference Regulatory Authorities	Ferinject 50 mg iron/mL solution for injection/infusion. By M/s Vifor France (MHRA approved)
	Me-too status	Ferinject 500mg/10ml by M/s RG. Pharmaceuticals (Reg#072548)
	GMP status	The firm has submitted copy of GMP certificate issued based on inspection conducted on 25-07-2019.
	Previous remarks of the Evaluator.	Confirmed as 2ml, 10 ml and 20ml vial in MHRA, UK.
	Previous Decision	Registration Board deferred the case for comments regarding patent status of applied formulation from legal division (M-292).
	Evaluation by PEC	The firm has submitted that Drug Registration Board has approved this formulation for various firms.
	Decision: Approved.	
450.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals and chemicals 25/1-3 sector 12-C, North Karachi industrial area, Karachi
	Brand Name +Dosage Form + Strength	Ispidon 175mg/25mg Tablet
	Composition	Each sustained release tablet contains: Propyphenazone……...175 mg Caffeine…….25 mg
	Diary No. Date of R& I & fee	Dy.No 1720, 30-08-2016, Rs.20,000/-
	Pharmacological Group	Other Analgesics and antipyretics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Optalidon Dragees of Perrigo spain (Spanish agency for medicines and health products)
	Me-too status	Optalidon of Novartis Pharma
	GMP status	Last GMP Inspection dated 12-6-17 with conclusive remarks of good cGMP compliance.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies can't be verified.
	Previous Decision	Deferred for revision of formulation as per reference product alongwith submission of applicable fee (M-307).
	Evaluation by PEC	Approval status of applied formulation has been verified in Spanish agency for medicines and health products. The firm has revised the formulation as per reference formulation as below: Each sugar coated tablet contains: Propyphenazone……...175 mg Caffeine…….25 mg Fee challan of Rs. 30,000/- (slip number: 53424604786) dated 13-06-2022 has been submitted for revision of formulation.
	Decision: Approved with Innovator's specifications and with following label claim. **Each sugar coated tablet contains:** **Propyphenazone……...175 mg** **Caffeine…….25 mg** • **Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
451.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd., Plot # 16, Zain park, Industrial Area, Saggian Bypass Road, Lahore
	Brand Name +Dosage Form + Strength	Hydrok oral liquid syrup
	Composition	Each 5ml contains: Diphenhydramine Hydrochloride…….13.5mg Ammonium Chloride…….131.5mg
	Diary No. Date of R& I & fee	Dy. No.4615; 1-06-2017; Rs.20,000/- (1-06-2017)
	Pharmacological Group	Antihistamine/expectorant
	Type of Form	Form-5

	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	90ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Benadryl original oral liquid by Johnson & Johnson Pacific Pty Ltd (TGA approved)
	Me-too status	B dryl cough syrup by Efroze
	GMP status	Last inspection report 20-1-2017 Panel recommended the grant of additional section.
	Previous remarks of the Evaluator.	International availability in RRA could not be confirmed.
	Previous Decision	Deferred for submission of evidence of approval in reference regulatory authorities (M-274)
	Evaluation by PEC	The firm has submitted that we may be allowed to correct the composition as Diphenhydramine hydrochloride 12.5mg/5ml instead of Diphenhydramine hydrochloride 13.5mg/5ml. Me-too: Sydinate Syrup of M/s Sayyed Pharma (Reg # 064310) The submitted me-too reference contains Dimenhydrinate instead of Diphenhydramine. Further, the product is not in line with international reference.
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

Case no. 02 Registration applications for local manufacturing of (Veterinary) drugs

a. Deferred cases

452.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	MYCOFAR-30 Injection
	Composition	Each ml contains: Tilmicosin as Phosphate……300mg
	Diary No. Date of R& I & fee	14257, 17-04-2018, 20,000/-, 16-04-2018
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	HICOS-300 INJECTION of M/s Hilton (Reg#043503)
	GMP status	The firm has submitted copy of GMP certificate issued based on inspection conducted on 02-07-2021.
	Previous remarks of the Evaluator.	The firm has provided Veterinary Liquid Injection (General) section. Salt form of applied formulation is not mentioned. Revision of Form-5 with requisite fee is required to be submitted.
	Previous decision(s)	Registration Board referred the case to QA & LT to update GMP status of the firm on priority (M-248).
	Evaluation by PEC	The firm has submitted copy of GMP certificate issued based on inspection conducted on 02-07-2021.
	Decision: Approved.	
453.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	ADENO-FAR Injection
	Composition	Each ml contains: Selenium …….0.50 mg

		Vitamin E Acetate……..70.0mg Vitamin B1……..20.0mg Vitamin B12……...0.010mg Adenosine-5 Phosphate……5.00mg
	Diary No. Date of R& I & fee	14258, 17-04-2018, 20,000/-, 13-04-2018
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml; Decontrolled
	Me-too status	SELPHOS Injection of M/s Selmore Pharma (Reg # 029647)
	GMP status	The firm has submitted copy of GMP certificate issued based on inspection conducted on 02-07-2021.
	Previous remarks of the Evaluator.	The submitted me-too reference is of different strength.
	Previous decision(s)	Registration Board referred the case to QA & LT to update GMP status of the firm on priority (M-248).
	Evaluation by PEC	The firm has submitted copy of GMP certificate issued based on inspection conducted on 02-07-2021. The submitted me-too reference is of different strength as under: EACH 100ML CONTAINS: - SELENIUM (AS SODIUM SELENITE) B.P. VET. 0.050GM. VITAMIN-E B.P./USP 7.00M. VITAMIN B-12 B.P/USP 0.010GM. VITAMIN B-1 B.P/USP 2.00M. ADENOSINE 5-MONOPHOSPHATE B.P/USP 0.500GM..
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
454.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	FLORO-FAR INJECTION
	Composition	Each ml contains: Florfenicol……400mg
	Diary No. Date of R& I & fee	14256, 17-04-2018, 20,000/-, 16-04-2018
	Pharmacological Group	Broad spectrum antibiotic
	Type of Form	Form-5
	Finished product Specification	In-house specification
	Pack size & Demanded Price	50 ml; Decontrolled
	Me-too status	Not submitted
	GMP status	The firm has submitted copy of GMP certificate issued based on inspection conducted on 02-07-2021
	Previous remarks of the Evaluator.	The me-too reference of applied formulation could not be verified from available database.
	Previous decision(s)	Registration Board referred the case to QA & LT to update GMP status of the firm on priority (M-248).
	Evaluation by PEC	The firm has submitted copy of GMP certificate issued based on inspection conducted on 02-07-2021. The firm has revised the composition as below: Each ml contains: Florfenicol……300mg Me-too: Neflox Injection of M/s Selmore Pharma (Reg # 049648)
	Decision: Approved with innovator's specifications and with following label claim: **Each ml contains:** **Florfenicol……300mg**	

	• **Registration Board further decided that registration letter will be issued after submission of 30,000/- fee for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
455.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	NITRO-FAR INJECTION
	Composition	Each ml contains: Nitroxynil……340mg
	Diary No. Date of R& I & fee	14255, 17-04-2018, 20,000/-, 16-04-2018
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	TROXY-34% INJECTION of M/s Selmore Pharma (Reg#034597)
	GMP status	The firm has submitted copy of GMP certificate issued based on inspection conducted on 02-07-2021.
	Previous remarks of the Evaluator.	Latest GMP inspection report which should have been conducted within period of 3 years is required to be submitted.
	Previous decision(s)	Registration Board referred the case to QA & LT to update GMP status of the firm on priority (M-248).
	Evaluation by PEC	The firm has submitted copy of GMP certificate issued based on inspection conducted on 02-07-2021.
	Decision: Approved with innovator's specifications. • **Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
456.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceutical (Pvt) Ltd, 23 Km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Renotone Plus oral Powder
	Composition	Each 1000gm contains: Hexamine……...…480gm Sodium Acid Phosphate…….160gm Ascorbic acid……...30gm Trihydroxyethyl Rutin…..….3gm
	Diary No. Date of R& I & fee	18-01-2011 vide diary No. 381 Rs.8,000 & 30-07-2013 vide diary No. 937 Rs.12000
	Pharmacological Group	Anti-Infective
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	Decontrolled/ 100gm, 250gm, 500gm, 1000gm &2.5 Kg.
	Me-too status	Exitone Oral Powder of M/s A & K Pharma (Reg#033289)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 13-08-2020.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following (M-265) Complete product specifications Last GMP inspection report conducted within one year Clarification regarding availability of potentiometer as claimed by applicant for analysis of API.
	Evaluation by PEC	The firm has claimed manufacturer's specifications. The firm is granted GMP certificate based on inspection conducted on 13-08-2020.
	Decision: Referred to Expert Working Group on Veterinary Drugs for review of applied formulation for the intended role as "Anti-infective".	
457.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceutical (Pvt) Ltd, 23 Km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Delta Mall Solution 2.5%

	Composition	Each ml contains: Deltamethrin…….. 2.5% w/v
	Diary No. Date of R& I & fee	04-06-2012, Rs.8000/-, 30-07-2013, Rs. 12000 /-
	Pharmacological Group	Disinfectant
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	Decontrolled/ 100ml, 250ml, 500ml, 1000ml & 2.5 L
	Me-too status	I-Dmeth Solution of International Pharma Labs (Reg#052388)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 13-08-2020.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for reference of finished product specification (M-265).
	Evaluation by PEC	The firm has claimed BP specifications for finished product.
	Decision: Approved with BP specifications. • **Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

Case No.02: Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

458.	Name and address of manufacturer / Applicant	M/s Hudson Pharma (pvt.) Ltd., D-93, North Western industrial Zone, Port Qasim, Karachi
	Brand Name +Dosage Form + Strength	LULISON CREAM 1%
	Composition	Each gm contains: Luliconazole……..…10mg
	Diary No. Date of R& I & fee	Dy No. 3791, 30-01-2018, Rs. 50,000/-,17-01-2018
	Pharmacological Group	Antifungal agent
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	LUZU Cream of Medicis **(USFDA approved)**
	Me-too status	Not available
	GMP status	Routine GMP inspection conducted on 11-12-2017 concluded that the overall cGMP compliance of the firm with respect to building, facilities and procedures demonstrated at the time of inspection found at acceptable level.

STABILITY STUDY DATA	
Drug	LULISON CREAM 1%
Name of Manufacturer	M/s Hudson Pharma (pvt.) Ltd., D-93, North Western industrial Zone, Port Qasim, Karachi
Manufacturer of API	M/s Viwit Pharmaceutical Co., Ltd. 88 Weizhi Road, Tengzhou Biopharma Park, Shandong, China
API Lot No.	333001-201705001
Description of Pack (Container closure system)	Plastic tubes
Stability Storage Condition	Accelerated: 40˚C ± 2˚C/75%±5% RH Real Time: 30˚C ± 2˚C/65%±5% RH

Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Accelerated: 0,1,3,6 (Months) Real Time: 0,1,3,6 (Months)		
Batch No.	LCS04	LCS05	LCS06
Batch Size	200 tubes	200 tubes	200 tubes
Manufacturing Date	11-09-2017	13-09-2017	28-10-2017
Date of Initiation	13-09-2017	18-09-2017	31-10-2017
No. of Batches	03		
Date of Submission	29340 (03-09-2018)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA from M/s Viwit Pharmaceutical Co., Ltd., Shandong, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate for M/s Viwit Pharmaceutical Co., Ltd., Shandong, China issued by Tengzhou Food and Drug Administration of People's Republic of China. It is valid until 24-09-2017.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice attested by ADC, DRAP, Karachi dated 19-06-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 03-09-2018 vide diary no. 29340

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board decided to approve the registration of "Acneson Gel 5% (Dapsone)" by M/s Hudson Pharma (Pvt.) Ltd., D-93, North Western Industrial Zone, Port Qasim-Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Date of Inspection: 10-05-2018. • The HPLC software is 21 CFR compliant

<table>
<tr><td></td><td></td><td>• Audit trail reports on testing of finished product are available.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of commercial invoice attested by ADC, DRAP, Karachi dated 19-06-2017.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard & impurity standards.</td><td>The firm has not submitted copy of invoice of working standard.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate for M/s Viwit Pharmaceutical Co., Ltd., Shandong, China issued by Tengzhou Food and Drug Administration of People’s Republic of China. It is valid until 24-09-2017.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA of API submitted.
• Copy of COA of working standard has been submitted
• Copy of COA of impurity standard has not been submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has not submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has not submitted List of qualified staff involved in R&D department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOPs for the Pharmaceutical Development of Product.”</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>LCS01</td><td>200 Tubes</td><td>-----</td></tr>
<tr><td>LCS02</td><td>200 Tubes</td><td>-----</td></tr>
<tr><td>LCS03</td><td>200 Tubes</td><td>-----</td></tr>
<tr><td>LCS04</td><td>200 Tubes</td><td>11-09-2017</td></tr>
<tr><td>LCS05</td><td>200 Tubes</td><td>13-09-2017</td></tr>
<tr><td>LCS06</td><td>200 Tubes</td><td>28-10-2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No.</th><th>Batch size</th><th>Consumed in stability batches</th><th>Remaining Quanti Lab trials, QC sample and retenti</th></tr>
<tr><td>LCS01</td><td>200 Tubes</td><td>20g</td><td rowspan="6">10g,
10g,
10g</td></tr>
<tr><td>LCS02</td><td>200 Tubes</td><td>20g</td></tr>
<tr><td>LCS03</td><td>200 Tubes</td><td>20g</td></tr>
<tr><td>LCS04</td><td>200 Tubes</td><td>20g</td></tr>
<tr><td>LCS05</td><td>200 Tubes</td><td>20g</td></tr>
<tr><td>LCS06</td><td>200 Tubes</td><td>20g</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of digital data logger record of Accelerated stability chamber and real time chamber from 01-08-2017 to 28-02-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Luliconazole.</td></tr>
</table>

14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for Luliconazole Cream 1% along with Stability Study Reports.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted reports of real time stability studies (25°C ± 2°C/65 ± 5% RH) for 6 months and accelerated stability studies (40°C ± 2°C/75 ± 5% RH) for 36 months of Luliconazole.
16.	Analysis reports for excipients used.	The firm has submitted photocopy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	Not submitted
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies with Lulimac Cream manufactured by M/s. Optimus Pharma Pvt. Limited, Solan India with Batch No.OA7012B. The firm's product results are comparable to that of the comparator product.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports of Luliconazole Cream 1% from 13-09-2017 to 19-07-2018 has been submitted.

The firm has initiated stability studies on 13-09-2017 whereas firm was granted section approval letter for Cream/Ointment/Gel section from licensing on 21-02-2018.
Finished product specifications do not mention dissolution test for applied formulation. Similarly, comparative Dissolution Profile does not dissolution conditions under which dissolution was performed.
Decision: Registration Board after thorough discussion decided to reject the stability data on the basis of following reasons (M-287):
"Manufacturing of batches of applied formulation i.e. Cream before the approval of relevant section i.e. Cream/Ointment/ Gel section by Licensing Division, DRAP.

Evaluation by PEC: The firm has submitted that we have re-manufactured 03 stability batches and kept them on accelerated and ambient stability which is enclosed herewith.

STABILITY STUDY DATA

Drug	LULISON CREAM 1%		
Name of Manufacturer	M/s Hudson Pharma (pvt.) Ltd., D-93, North Western industrial Zone, Port Qasim, Karachi		
Manufacturer of API	M/s Viwit Pharmaceutical Co., Ltd. 88 Weizhi Road, Tengzhou Biopharma Park, Shandong, China		
API Lot No.	333001-201705001		
Description of Pack (Container closure system)	Plastic tubes		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 06 (months)	Real Time: 06 (months)	
Frequency	Accelerated: 0,1,3,6 (Months)	Real Time: 0,1,3,6 (Months)	
Batch No.	LCS07	LCS08	LCS09
Batch Size	200 tubes	200 tubes	200 tubes
Manufacturing Date	04-2019	04-2019	04-2019
Date of Initiation	19-04-2019	19-04-2019	19-04-2019
No. of Batches	03		
Date of Submission	21937 (25-10-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	**Documents To Be Provided**	**Status**

1.	Certificate of analysis of drug substance	Copy of COA from M/s Viwit Pharmaceutical Co., Ltd., Shandong, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate for M/s Viwit Pharmaceutical Co., Ltd., Shandong, China issued by Tengzhou Food and Drug Administration of People's Republic of China. It is valid until 24-09-2017.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice attested by ADC, DRAP, Karachi dated 19-06-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Batches.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of LULISON CREAM 1% (Luliconazole), Pack Size 1x10g by M/S. Hudson Pharma (Pvt) Ltd., D-93, North Western Industrial Zone, Post Qasim, Karachi.

Reference No: F.1-2/2020-PEC dated 29th March, 2021.
Investigation Date and Time: 05th January, 2022 (Morning).
Investigation Site: Factory premises of M/S. Hudson Pharma (Pvt) Ltd., Port Qasim Industrial Zone, Karachi.

Background:
Chairman Registration Board considered the applications of M/S. Hudson Pharma (Pvt) Ltd., Port Qasim, Karachi for registration of LULISON CREAM 1% (Luliconazole) 10mg and constituted a two member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:
1. Dr. Saif-ur-Rehman Khattak, Director/ FGA, CDL, Karachi.
2. Mr. Awais Ahmad, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:
Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:
The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Sr.#	Question	Observation

<table>
<tr><td>1.</td><td>Do you have documents confirming the import of Luliconazole API including approval from DRAP?</td><td>Luliconazole imported from Optrix laboratories Pvt Ltd, India with proper approval from DRAP Karachi with following details.
<table>
<tr><td>Batch No.</td><td>Date of Import</td><td>Invoice No.</td><td>Quantity Imported</td></tr>
<tr><td>OT-LCZ/04/17/002</td><td>27/10/2017</td><td>035</td><td>150 g</td></tr>
</table>
As per PEC observation the firm to adjust the pH again manufactured 3 new batches of Lulison cream for which they procured API Luliconazole from same source, Optrix laboratories Pvt Ltd, India, with following details:
<table>
<tr><td>Batch No.</td><td>Date of Import</td><td>Invoice No.</td><td>Quantity Imported</td></tr>
<tr><td>1/OT-LCZ/S2/013/21</td><td>29/07/21</td><td>SS-02482</td><td>110 g</td></tr>
</table></td></tr>
<tr><td>2.</td><td>What was the rationale behind selecting the particular manufacturer of API?</td><td>The rationale for selection of API manufacturer is the vendor qualification criteria as per SOP # QA/GN/OP/023 that contains GMP Certificate, DMF, SMF, API, Impurity standards etc.</td></tr>
<tr><td>3.</td><td>Do you have documents confirming the import of Luliconazole reference standard and impurity standards?</td><td>The firm has imported Luliconazole working standard and impurity standards from Optrix laboratories India.</td></tr>
<tr><td>4.</td><td>Do you have a certificate of Analysis of the API, reference standards and impurity standards?</td><td>The firm has COA for the API, working standards and impurity standards.</td></tr>
<tr><td>5.</td><td>Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?</td><td>The firm has a copy of GMP certificate of Optrix Laboratories Pvt Ltd India issued by regulatory authority of India valid upto 02/06/2025.</td></tr>
<tr><td>6.</td><td>Do you use API manufacturer methods of testing?</td><td>The firm has used an in-house method for testing of Luliconazole based on API manufacturer method of testing.</td></tr>
<tr><td>7.</td><td>Do you have stability studies reports on API?</td><td>The firm has real time & accelerated stability study reports of Luliconazole conducted by the API manufacturer.</td></tr>
<tr><td>8.</td><td>If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?</td><td>The stability testing has been performed as per SIM method.</td></tr>
<tr><td>9.</td><td>Do you have a method for quantifying the impurities in the API?</td><td>The firm has a method for quantifying the impurities in the API based on manufacturer specification.</td></tr>
<tr><td>10.</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>The firm has some remaining quantity of API, impurities and reference standard procured for the new batches.</td></tr>
</table>

<table>
<tr><td>11.</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm has used the following pharma grade excipients.
Benzyl alcohol from Sigma Aldrich, USA.
Butylated Hydroxy toluene from Hangzhou Zhongbao Import & Export Corp Ltd, China.
Cetostearyl alcohol from Emery, Malaysia.
Isopropyl myristate from KLK Oleo, Malaysia.
Caprylic Capric Triglyceride from KLK Oleo, Malaysia.
Methylparaben from UENO Fine Chemicals, Japan.
Polysorbate 60 (tween 60) from Croda, India.
Propylene glycol from Merck, Germany.
Sorbitan monostearate (Span 60) from Croda, India.</td></tr>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>All the excipients have been locally purchased, with proper invoice and COAs.</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has test reports & other records on the excipients used.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of Lulison cream 1%?</td><td>The firm has written & authorized protocols for the development of Lulison 1% cream.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipients compatibility studies?</td><td>Since the firm has used the same excipient as used by innovator (Luzu 1% Cream), therefore compatibility studies are not needed.</td></tr>
<tr><td>16.</td><td>Have you performed comparative studies?</td><td>The firm has not performed comparative studies, with innovator product.</td></tr>
<tr><td>17.</td><td>Do you have a product development (R&D) section?</td><td>The firm has a product development section.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in the product development section for development of Lulison cream 1%?</td><td>The firm has necessary equipment is PD section for manufacturing while for QC routine QC equipment are used.</td></tr>
<tr><td>19.</td><td>Are the equipment in the product development section qualified?</td><td>All the equipment are qualified.</td></tr>
<tr><td>20.</td><td>Do you have a proper maintenance / calibration / re-qualification program for the equipment used in the PD section?</td><td>There is a proper maintenance & calibration / re-qualification program for the equipment used in the PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in the product development section with proper knowledge and training in product development?</td><td>The firm has 2 Pharmacists assisted by the staff of manufacturing & QC, in product development.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Lulison cream 1% as required?</td><td>The firm has manufactured three stability batches for the stability study of Lulison cream(pH:3-4.5), with details as below:
<table>
<tr><td>Batch No.</td><td>Mfg. Date</td><td>Batch Size</td></tr>
<tr><td>LCS07</td><td>09-04-2019</td><td>200 tubes each of 10g</td></tr>
<tr><td>LCS08</td><td>15-04-2019</td><td>200 tubes each of 10g</td></tr>
<tr><td>LCS09</td><td>16-04-2019</td><td>200 tubes each of 10g</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td>The firm has further manufactured three stability batches for the stability study of Lulison cream (pH:5-7) as per PEC recommendations with details as below:
<table>
<tr><td>Batch No.</td><td>Mfg. Date</td><td>Batch Size</td></tr>
<tr><td>SB-LUL-CR-01</td><td>07-09-2021</td><td>250 tubes each of 10g</td></tr>
<tr><td>SB-LUL-CR-02</td><td>20-09-2021</td><td>250 tubes each of 10g</td></tr>
<tr><td>SB-LUL-CR-03</td><td>25-09-2021</td><td>250 tubes each of 10g</td></tr>
</table></td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The firm has manufactured stability batches based on number of tests & frequency of testing.</td></tr>
<tr><td>24.</td><td>Do you have a complete record of production of stability batches?</td><td>The firm has a complete record of production of stability batches.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has developed protocol for stability testing of stability batches (Doc#QC/GN/OP/015).</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed & validated methods for testing of stability batches of Lulison 1% cream.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>N/A</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Luliconazole and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment/instruments being used in the test & analysis of Luliconazole & the finished product (Lulison 1% Cream).</td></tr>
<tr><td>29.</td><td>Does your method of analysis stability indicating?</td><td>The firm has performed analytical method validation on their product forced degradation studies from basis for the method to be stability indicating.</td></tr>
<tr><td>30.</td><td>Does your HPLC software is 21CFR compliant?</td><td>The firm has HPLC software is 21CFR compliant.</td></tr>
<tr><td>31.</td><td>Can you show Audit Trail reports on Luliconazole testing?</td><td>Audit trail reports on testing of API and finished product is available.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>Impurities studies are available.</td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>The three new batches manufactured in July 2021 have been kept for stability testing. Currently three months studies are complete with satisfactory results.</td></tr>
<tr><td>34.</td><td>Do you have valid calibration status for the equipments used in Lulison cream 1% production & analysis?</td><td>The firm has valid calibration status for the equipment used in the production & analysis of lulison cream 1%.</td></tr>
<tr><td>35.</td><td>Do proper and continuous monitoring and control are available for the stability chamber?</td><td>Adequate monitoring & controls are available for stability chambers. Chambers are controlled & monitored through data loggers.</td></tr>
</table>

36.	Do related manufacturing area, equipments, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel & utilities are GMP compliant.
37.	Queries of PEC: Results of pH of applied formulation in the light of innovator product (LUZU 1% w/w cream) having pH accepting criteria ranging from 5.0 to 7.0. Performance of test of viscosity and homogeneity for evaluation of topical formulation.	Firm has shown studies on two different formulations manufactured at pH specs as 3.0 to 4.5 and 5.0 to 7.0. respectively. Six months studies conducted at real time and accelerated conditions on three batches of the first formulation have been already submitted to Islamabad. Three batches of the second formulation having pH specs 5.0 to 7.0 have been kept on real time and accelerated condition. Currently three months studies are complete which are being evaluated by the panel. The studies with both the formulation demonstrate that the product is stable within a pH range of 3.0 to 7.0. The firm has also submitted their safety testing on both formulations for acute dermal irritant test. The results of the test show that no sign of irritation / inflammation were found during the observation period of (optimized test conditions). (Copy of Reports Attached). Firm has also performed viscosity testing on the manufactured batches from PCSIR. The results are within the range i.e. 20,000 to 40,000 (common ranges for cream formulation). (Copy of Report Attached).

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Lulison 1% Cream Pack Size 1x10g are verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Lulison 1% Cream Pack Size 1x10g.

Recommendations:

The panel recommends registration of Lulison 1% Cream (Luliconazole).

Decision: Deferred for submission of following:

<table>
<tr><th>Sr. #</th><th>Decision of 316th meeting</th><th>Response by the firm</th></tr>
<tr><td>1.</td><td>Stability data, upto 6th month time point, of the trial batches which were presented before inspection panel with pH specifications of 5.0 to 7.0.</td><td>The firm has submitted 06 m onths stability study data including raw data sheets, chromatograms, audit trail and digital data logger.
<table>
<tr><td>Batch No.</td><td>SB-LUL-CR-01</td><td>SB-LUL-CR-02</td><td>SB-LUL-CR-03</td></tr>
<tr><td>Batch Size</td><td>250tubes</td><td>250 tubes</td><td>250 tubes</td></tr>
<tr><td>Manufacturing Date</td><td>07-2021</td><td>07-2021</td><td>07-2021</td></tr>
<tr><td>Date of Initiation</td><td>07-09-2021</td><td>29-09-2021</td><td>29-09-2021</td></tr>
<tr><td>No. of Batches</td><td colspan="3">03</td></tr>
</table></td></tr>
<tr><td>2.</td><td>Pharmaceutical equivalence with innovator / reference drug product shall also be submitted.</td><td>The firm has submitted pharmaceutical equivalence with reference product Luzu Cream (Batch # LOT8131016) of M/s Valent pharmaceuticals by performing Identification, pH and Assay.</td></tr>
<tr><td>3.</td><td>Firm shall also submit fee of Rs. 30,000 for revision in stability data, as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.</td><td>The firm has submitted fee of Rs. 30,000 vide slip number 2581583454 for revision in stability data, as per notification.</td></tr>
</table>

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**
- **Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Case No. 3 Registration applications for local manufacturing of human drugs submitted on CTD format

Deferred cases (New License):

On the recommendations of panel of experts, the CLB in its 276th meeting held on 03rd September, 2020 has considered and approved the grant of Drug Manufacturing License in the name of M/s Alpenglow pharmaceuticals (Pvt) Ltd, Plot No. A7, Risalpur Export processing Zone, Risalpur.

i. Capsule (Cephalosporin)
ii. Dry Powder injection section (Cephalosporin) (1 molecule / 6 products)
iii. Dry powder suspension section (Cephalosporin)
iv. Tablet (Psychotropic)

459.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5231 Dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	CIAXON 250mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as Sodium……..250mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 250mg IV Injection USFDA Approved.
	For generic drugs (me-too status)	AVENTRIAX 250mg IV Injection
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.

	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of ceftriaxone sodium is present in USP. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (011302001, 011302002, 011302003).
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against comparator product Aventrix 250mg Injection by Sanofi Aventis Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA	
Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.
API Lot No.	Q0121039028
Description of Pack (Container closure system)	Transparent PVC tray Sealed with printed A.foil filled with Dry Sterile Powder ceftriaxone in clear glass vial One Ampoule of water

	for injection and aluminum Foil with embossed board unit carton UV coated. (1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	2000 Vials	2000 Vials	2000 Vials
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	09-06-2021	09-06-2021	09-06-2021
No. of Batches	03		

DOCUMENTS/DATA ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. SX20180229 issued by CFDA valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.0090/2021/DRAP-CPS/1330 CD(I&E) dated 16/04/2021 wherein the permission to import different APIs like ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. AHPAO505150 dated 04-05-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	Observations communicated	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Copies of drug substance specifications and analytical procedures were provided by drug substance manufacturer. However, copies of drug substance specifications and analytical procedures were not provided by drug product manufacturer.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The submitted analytical method verification studies were performed by drug substance manufacturer. Method verification studies were not performed by drug product manufacturer.
3.	The tests for crystallinity and particulate matter are not performed by drug product manufacturer.	Not submitted.

<table>
<tr><td></td><td>The assay limit specified by drug substance manufacturer (>84.0%) is different from that specified by drug product manufacturer (NLT 79%). Justification is required.</td><td>Assay limit as specified by drug substance manufacturer > 84% is according to CP 2010 as provided by Sinopharm.
While QC department of Alpenglow has followed USP 43 which specifies assay limit = NLT 79%.</td></tr>
<tr><td>4.</td><td>Provide COA of reference standard which is actually used in the analysis of drug substance.</td><td>Instead of providing CoA from drug substance manufacturer, the firm has provided CoA of working standard of FPP manufacturer.</td></tr>
<tr><td>5.</td><td>Submit master formulation including theoretical fill weight per vial.</td><td>The firm has provided theoretical fill weight of ceftriaxone sodium per vial.</td></tr>
<tr><td>6.</td><td>Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.</td><td>Not submitted.</td></tr>
<tr><td>7.</td><td>Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.</td><td>Not submitted.</td></tr>
<tr><td>8.</td><td>Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.</td><td>Not submitted.</td></tr>
<tr><td>9.</td><td>Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.</td><td>The firm has provided testing method of ceftriaxone sodium raw material. The chromatographic conditions are different from USP.
<table>
<tr><th>Parameters</th><th>Submitted monograph</th><th>USP monograph</th></tr>
<tr><td>Column</td><td>4mm × 15cm packing L1</td><td>4.6-mm × 25-cm; 5-µm packing</td></tr>
<tr><td>Flow rate</td><td>2.0 ml/min</td><td>1.5 ml/min</td></tr>
<tr><td>Detector</td><td>270nm</td><td>UV 254 nm</td></tr>
<tr><td>Mobile phase</td><td>Tetraheptyl ammonium bromide in 400ml of acetonitrile</td><td>Tetradecyl ammonium bromide and tetraheptyl ammonium bromide in a mixture of 440 mL of water, 55 mL of Buffer, 5.0 mL of Solution C, and 500 mL of acetonitrile.</td></tr>
</table></td></tr>
<tr><td>10.</td><td>Provide standard and sample preparation method used in analytical method verification studies.</td><td>Not submitted.</td></tr>
<tr><td>11.</td><td>Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies.</td><td>Not submitted</td></tr>
<tr><td>12.</td><td>Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required.
Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by</td><td>The firm has submitted analytical method verification studies of drug product including specificity, accuracy and precision.</td></tr>
</table>

	the Drug Product manufacturer shall be submitted. The peak area of standard solution concentration in analytical method verification studies is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately. Clarify the difference in peak areas.	Not submitted.
13.	Provide COA of reference standard actually used in the analysis of drug product.	The firm has submitted COA of working standard from drug product manufacturer.
14.	• In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided. • The tests for water contents, constituted solution etc are not performed during stability studies since these tests are required to make assessment of the stability profile. • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. Reference of previous approval of applications with stability study data of the firm (if any).	Not submitted Not provided The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
15.	• Pharmaceutical equivalence of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted.	The firm has submitted pharmaceutical equivalence data against Rocephin 250mg IV injection (batch # 4121z015) by performing quality tests.

Decision: Deferred for following:

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification studies for testing of ceftriaxone sodium as per USP recommendations.
2.	Performance of tests of crystallinity and particulate matter by drug product manufacturer.	The tests were performed as per USP monograph. The crystallinity test was performed however, particulate matter test was performed for product.
3.	Justify the difference in assay limit specified by drug substance manufacturer (>84.0%) and drug product manufacturer (NLT 79%).	The drug substance manufacturer follows USP as well as Chinese pharmacopoeia monograph for ceftriaxone sodium, so claims the assay limit > 84%. While being the drug product manufacturer we have followed the USP monograph for ceftriaxone and USP specifies the limit of NLT 79.5%.
4.	Justify the chromatographic conditions in the submitted analytical procedures which are different from USP monograph.	The chromatographic conditions specified in analytical procedure are as per older version of USP 29. We have updated the specifications according to the latest version of USP. The product was tested in accordance with updated conditions and the results were found satisfactory and within limits.

5.	Submit master formulation including details of potency adjustment as per assay results on certificate of analysis.	The firm has submitted master formulation with calculations of fill weight as per assay result on certificate of analysis.
6.	Justification of submission of pharmaceutical equivalence data with Rocephin 250mg IV Injection since the formulation in the same strength is not available.	The firm has submitted pharmaceutical equivalence study with comparator product Oxidil 250mg injection (Batch # 002H) of Sami Pharma by performing tests of Identification, pH, Clarify of solution and assay.
7.	Performance of compatibility studies for the dry powder for injections as per the instructions provided in individual label of the drug product.	Sterile water for injection is the recommended diluent for intravenous injection of ceftriaxone sodium prior to administration. The results of compatibility and reconstitution studies are provided.
8.	Provide standard and sample preparation method used in analytical method verification studies.	The firm has provided methods for standard and sample preparation used in method verification studies of drug product.
9.	Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	The firm has specified the concentrations of 80% (0.24mg/ml), 100% (0.30mg/ml) and 120% (0.36mg/ml) used in accuracy studies. Moreover, details of blank solution, placebo and sample solution were provided specificity study.
10.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted method verification studies of drug product as per the USP recommendation.
11.	Clarify the difference in peak area for standard solution concentration in analytical method verification studies which is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately.	The reason for area difference was that in verification studies the injection volume was different. The change in injection volume was a deviation to USP method, so the method was re-verified using standard USP method without any deviation. The area obtained was approximately same as that in stability studies.
12.	Provide COA of reference standard actually used in the analysis of drug product.	COA of USP primary reference standard with lot no: H0J296 has been provided.
13.	Provide in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	The product is recommended to be used instantly after reconstitution, however if stored in refrigerator the product can be used in 24 h. So 24 h in-use stability study was performed.
14.	Performance of tests for water contents, constituted solution etc during stability studies since these tests are required to make assessment of the stability profile.	The firm has submitted that the constituted solution was checked at every point of stability study since the assay is performed after reconstituting the injection. After reconstitution and before assay, the injection was checked for particulate matter or other foreign matter. The revised stability summary sheets were provided.
15.	Evidence of procurement of API with approval from DRAP.	The firm has submitted copy of invoice specifying import of Ceftriaxone sodium 50Kg (Batch # Q012102085) attested by Assistant Director (I & E), Peshawar dated 16-04-2021.

Decision: Approved.

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

460.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.

	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.5233 Dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	CIAXON 250mg IM Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as Sodium……250mg
	Pharmaceutical form of applied drug	Intramuscular Injection
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 250mg IM Injection USFDA Approved.
	For generic drugs (me-too status)	AVENTRIAX 250mg IM inj
	GMP status of the Finished product manufacturer	New license granted on 22/09/2020 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ceftrioxone Sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its

		verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (011302001, 011302002, 011302003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the brand leader that is Aventrix 250mg Injection by Sanofi Aventis Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.		
API Lot No.	Q0121039028		
Description of Pack (Container closure system)	Transparent PVC tray Sealed with printed Alu foil filled with Dry Sterile Powder ceftriaxone in clear glass vial One Ampoule of water for injection and aluminum Foil with embossed board unit carton UV coated. (1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	004	005	006
Batch Size	2000 Vials	2000 Vials	2000 Vials
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	09-06-2021	09-06-2021	09-06-2021
No. of Batches	03		

DOCUMENTS/DATA ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SX20180229 issued by CFDA valid till 05/06/2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.0090/2021/DRAP-CPS/1330 CD(I&E) dated 16/04/2021 is submitted wherein the permission to import different APIs ceftriaxone as sodium for the purpose of test/analysis and stability studies is granted. AHPAO505150 dated 04/05/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Observations communicated	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Copies of drug substance specifications and analytical procedures were provided by drug substance manufacturer.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The submitted analytical method verification studies were performed by drug substance manufacturer. Method verification studies were not performed by drug product manufacturer.
3.	The tests for crystallinity and particulate matter are not performed by drug product manufacturer. The assay limit specified by drug substance manufacturer (>84.0%) is different from that specified by drug product manufacturer (NLT 79%). Justification is required.	Not submitted. Assay limit as specified by drug substance manufacturer > 84% is according to CP 2010 as provided by Sinopharm. While QC department of Alpenglow has followed USP 43 which specifies assay limit = NLT 79%.
4.	Provide COA of reference standard which is actually used in the analysis of drug substance.	Instead of providing CoA from drug substance manufacturer, the firm has provided CoA of working standard of FPP manufacturer.
5.	Submit master formulation including theoretical fill weight per vial.	The firm has provided theoretical fill weight of ceftriaxone sodium per vial.
6.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Not submitted
7.	Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.	Not submitted
8.	Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.	Not submitted
9.	Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.	The firm has provided testing method of ceftriaxone sodium raw material. The

<table>
<tr><td></td><td></td><td>chromatographic conditions are different from USP.
<table>
<tr><td>Parameters</td><td>Submitted monograph</td><td>USP monograph</td></tr>
<tr><td>Column</td><td>4mm × 15cm packing L1</td><td>4.6-mm × 25-cm; 5-µm packing</td></tr>
<tr><td>Flow rate</td><td>2.0 ml/min</td><td>1.5 ml/min</td></tr>
<tr><td>Detector</td><td>270nm</td><td>UV 254 nm</td></tr>
<tr><td>Mobile phase</td><td>Tetraheptyl ammonium bromide in 400ml of acetonitrile</td><td>Tetradecyl ammonium bromide and tetraheptyl ammonium bromide in a mixture of 440 mL ofwater, 55 mL of Buffer, 5.0 mL of Solution C, and 500 mL of acetonitrile.</td></tr>
</table></td></tr>
<tr><td>10.</td><td>Provide standard and sample preparation method used in analytical method verification studies.</td><td>Not submitted.</td></tr>
<tr><td>11.</td><td>Specify the details of the accuracy and specificity test including the details of concertation of 80%, 100% and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies.</td><td></td></tr>
<tr><td>12.</td><td>Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required.
Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.
The peak area of standard solution concentration in analytical method verification studies is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately. Clarify the difference in peak areas.</td><td>The firm has submitted analytical method verification studies of drug product including specificity, accuracy and precision.

Not submitted.</td></tr>
<tr><td>13.</td><td>Provide COA of reference standard actually used in the analysis of drug product.</td><td>The firm has submitted COA of working standard from drug product manufacturer.</td></tr>
<tr><td>14.</td><td>• In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.
• Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch.
• The tests for water contents, constituted solution etc are not performed during stability</td><td>Not submitted

Not submitted

Not provided</td></tr>
</table>

	studies since these tests are required to make assessment of the stability profile. • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. Reference of previous approval of applications with stability study data of the firm (if any).	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
15.	• Pharmaceutical equivalence of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted.	The firm has submitted pharmaceutical equivalence data against Rocephin 250mg IM injection (batch # 4121z015) by performing quality tests.

Deferred for following:

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification studies for testing of ceftriaxone sodium as per USP recommendations.
2.	Performance of tests of crystallinity and particulate matter by drug product manufacturer.	The tests were performed as per USP monograph. The crystallinity test was performed however, particulate matter test was performed for product.
3.	Justify the difference in assay limit specified by drug substance manufacturer (>84.0%) and drug product manufacturer (NLT 79%).	The drug substance manufacturer follows USP as well as Chinese pharmacopoeia monograph for ceftriaxone sodium, so claims the assay limit > 84%. While being the drug product manufacturer we have followed the USP monograph for ceftriaxone and USP specifies the limit of NLT 79.5%.
4.	Justify the chromatographic conditions in the submitted analytical procedures which are different from USP monograph.	The chromatographic conditions specified in analytical procedure are as per older version of USP 29. We have updated the specifications according to the latest version of USP. The product was tested in accordance with updated conditions and the results were found satisfactory and within limits.
5.	Submit master formulation including details of potency adjustment as per assay results on certificate of analysis.	The firm has submitted master formulation with calculations of fill weight as per assay result on certificate of analysis.
6.	Justification of submission of pharmaceutical equivalence data with Rocephin 250mg IV Injection since the formulation in the same strength is not available.	The firm has submitted pharmaceutical equivalence study with comparator product Oxidil 250mg injection (Batch # 002H) of Sami Pharma by performing tests of Identification, pH, Clarify of solution and assay.
7.	Performance of compatibility studies for the dry powder for injections as per the instructions provided in individual label of the drug product.	Sterile lignocaine for injection is the recommended diluent for intravenous injection of ceftriaxone sodium prior to administration. The results of compatibility and reconstitution studies are provided.
8.	Provide standard and sample preparation method used in analytical method verification studies.	The firm has provided methods for standard and sample preparation used in method verification studies of drug product.
9.	Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	The firm has specified the concentrations of 80% (0.24mg/ml), 100% (0.30mg/ml) and 120% (0.36mg/ml) used in accuracy studies. Moreover, details of blank solution, placebo and

		sample solution were provided specificity study.
10.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted method verification studies of drug product as per the USP recommendation.
11.	Clarify the difference in peak area for standard solution concentration in analytical method verification studies which is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately.	The reason for area difference was that in verification studies the injection volume was different. The change in injection volume was a deviation to USP method, so the method was re-verified using standard USP method without any deviation. The area obtained was approximately same as that in stability studies.
12.	Provide COA of reference standard actually used in the analysis of drug product.	COA of USP primary reference standard with lot no: H0J296 has been provided.
13.	Provide in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	The product is recommended to be used instantly after reconstitution, however if stored in refrigerator the product can be used in 24 h. So 24 h in-use stability study was performed.
14.	Performance of tests for water contents, constituted solution etc during stability studies since these tests are required to make assessment of the stability profile.	The firm has submitted that the constituted solution was checked at every point of stability study since the assay is performed after reconstituting the injection. After reconstitution and before assay the injection was checked for particulate matter or other foreign matter. The revised stability summary sheets were provided.
15.	Evidence of procurement of API with approval from DRAP.	The firm has submitted copy of invoice specifying import of Ceftriaxone sodium 50Kg (Batch # Q012102085) attested by Assistant Director (I & E), Peshawar dated 16-04-2021.

Decision: Approved.

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

461.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.5234 Dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	CIAXON 500mg IM Injection

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as Sodium……..500 mg
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 500mg IM Injection USFDA Approved.
	For generic drugs (me-too status)	AVENTRIAX 500mg IM injection
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of ceftriaxone sodium is present in USP. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (011302001, 011302002, 011302003)
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Aventrix 500mg IM Injection by Sanofi Aventis Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/S Sinopharm Weiqida Pharmaceutical Co. Ltd., First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.		
API Lot No.	Q0121039028		
Description of Pack (Container closure system)	Transparent PVC tray Sealed with printed A.foil filled with Dry Sterile Powder ceftriaxone in clear glass vial One Ampoule of water for injection and aluminum Foil with embossed board unit carton UV coated. (1's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	010	011	012
Batch Size	1200 Vials	1200 Vials	1200 Vials
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	09-06-2021	09-06-2021	09-06-2021
No. of Batches	03		

DOCUMENTS/DATA ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any).	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. SX20180229 issued by CFDA valid till 05/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.0090/2021/ DRAP-CPS/1330 CD (I&E) dated 16-04-2021 wherein the permission to import different APIs including ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. AHPAO505150 dated 04-05-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:

Sr. No.	Observations communicated	Response by the firm

<table>
<tr><td>1.</td><td>Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.</td><td>Copies of drug substance specifications and analytical procedures were provided by drug substance manufacturer.</td></tr>
<tr><td>2.</td><td>Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.</td><td>The submitted analytical method verification studies were performed by drug substance manufacturer. Method verification studies were not performed by drug product manufacturer.</td></tr>
<tr><td>3.</td><td>The tests for crystallinity and particulate matter are not performed by drug product manufacturer.
The assay limit specified by drug substance manufacturer (>84.0%) is different from that specified by drug product manufacturer (NLT 79%). Justification is required.</td><td>Not submitted.

Assay limit as specified by drug substance manufacturer > 84% is according to CP 2010 as provided by Sinopharm.
While QC department of Alpenglow has followed USP 43 which specifies assay limit = NLT 79%.</td></tr>
<tr><td>4.</td><td>Provide COA of reference standard which is actually used in the analysis of drug substance.</td><td>Instead of providing CoA from drug substance manufacturer, the firm has provided CoA of working standard of FPP manufacturer.</td></tr>
<tr><td>5.</td><td>Submit master formulation including theoretical fill weight per vial.</td><td>The firm has provided theoretical fill weight of ceftriaxone sodium per vial.</td></tr>
<tr><td>6.</td><td>Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.</td><td>Not submitted</td></tr>
<tr><td>7.</td><td>Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.</td><td>Not submitted</td></tr>
<tr><td>8.</td><td>Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.</td><td>Not submitted</td></tr>
<tr><td>9.</td><td>Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.</td><td>The firm has provided testing method of ceftriaxone sodium raw material. The chromatographic conditions are different from USP.
<table>
<tr><td>Parameters</td><td>Submitted monograph</td><td>USP monograph</td></tr>
<tr><td>Column</td><td>4mm × 15cm packing L1</td><td>4.6-mm × 25-cm; 5-µm packing</td></tr>
<tr><td>Flow rate</td><td>2.0 ml/min</td><td>1.5 ml/min</td></tr>
<tr><td>Detector</td><td>270nm</td><td>UV 254 nm</td></tr>
<tr><td>Mobile phase</td><td>Tetraheptyl ammonium bromide in 400ml of acetonitrile</td><td>Tetradecyl ammonium bromide and tetraheptyl ammonium bromide in a mixture of 440 mL ofwater, 55 mL of Buffer, 5.0 mL of Solution C, and 500 mL of acetonitrile.</td></tr>
</table></td></tr>
<tr><td>10.</td><td>Provide standard and sample preparation method used in analytical method verification studies.</td><td>Not submitted.</td></tr>
<tr><td>11.</td><td>Specify the details of the accuracy and specificity test including the details of</td><td></td></tr>
</table>

	concertation of 80%, 100% and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies.	
12.	Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required. Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. The peak area of standard solution concentration in analytical method verification studies is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately. Clarify the difference in peak areas.	The firm has submitted analytical method verification studies of drug product including specificity, accuracy and precision. Not submitted.
13.	Provide COA of reference standard actually used in the analysis of drug product.	The firm has submitted COA of working standard from drug product manufacturer.
14.	• In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided. The tests for water contents, constituted solution etc are not performed during stability studies since these tests are required to make assessment of the stability profile. Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. Reference of previous approval of applications with stability study data of the firm (if any).	Not submitted Not provided The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
15.	• Pharmaceutical equivalence of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted.	The firm has submitted pharmaceutical equivalence data against Rocephin 500mg IM injection (batch # 4121z015) by performing quality tests.

Deferred for submission of following:

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification studies for testing of ceftriaxone sodium as per USP recommendations.
2.	Performance of tests of crystallinity and particulate matter by drug product manufacturer.	The tests were performed as per USP monograph. The crystallinity test was performed however, particulate matter test was performed for product.
3.	Justify the difference in assay limit specified by drug substance manufacturer (>84.0%) and drug product manufacturer (NLT 79%).	The drug substance manufacturer follows USP as well as Chinese pharmacopoeia monograph for ceftriaxone sodium, so claims the assay limit > 84%. While being the drug product manufacturer we have followed the USP monograph for

		ceftriaxone and USP specifies the limit of NLT 79.5%.
4.	Justify the chromatographic conditions in the submitted analytical procedures which are different from USP monograph.	The chromatographic conditions specified in analytical procedure are as per older version of USP 29. We have updated the specifications according to the latest version of USP. The product was tested in accordance with updated conditions and the results were found satisfactory and within limits.
5.	Submit master formulation including details of potency adjustment as per assay results on certificate of analysis.	The firm has submitted master formulation with calculations of fill weight as per assay result on certificate of analysis.
6.	Performance of compatibility studies for the dry powder for injections as per the instructions provided in individual label of the drug product.	Sterile lignocaine for injection is the recommended diluent for intravenous injection of ceftriaxone sodium prior to administration. The results of compatibility and reconstitution studies are provided.
7.	Provide standard and sample preparation method used in analytical method verification studies.	The firm has provided methods for standard and sample preparation used in method verification studies of drug product.
8.	Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	The firm has specified the concentrations of 80% (0.24mg/ml), 100% (0.30mg/ml) and 120% (0.36mg/ml) used in accuracy studies. Moreover, details of blank solution, placebo and sample solution were provided specificity study.
9.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted method verification studies of drug product as per the USP recommendation.
10.	Clarify the difference in peak area for standard solution concentration in analytical method verification studies which is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately.	The reason for area difference was that in verification studies the injection volume was different. The change in injection volume was a deviation to USP method, so the method was re-verified using standard USP method without any deviation. The area obtained was approximately same as that in stability studies.
11.	Provide COA of reference standard actually used in the analysis of drug product.	COA of USP primary reference standard with lot no: H0J296 has been provided.
12.	Provide in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	The product is recommended to be used instantly after reconstitution, however if stored in refrigerator the product can be used in 24 h. So 24 h in-use stability study was performed.
13.	Performance of tests for water contents, constituted solution etc during stability studies since these tests are required to make assessment of the stability profile.	The firm has submitted that the constituted solution was checked at every point of stability study since the assay is performed after reconstituting the injection. After reconstitution and before assay the injection was checked for particulate matter or other foreign matter. The revised stability summary sheets were provided.
14.	Evidence of procurement of API with approval from DRAP.	The firm has submitted copy of invoice specifying import of Ceftriaxone sodium 50Kg (Batch # Q012102085) attested by Assistant Director (I & E), Peshawar dated 16-04-2021.

Decision: Approved.

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

• **Manufacturer will submit results of pharmaceutical equivalence against the innovator's product before issuance of Registration Letter.**		
462.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5232 Dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	CIAXON 500mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as sodium…….500 mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 500mg IV Injection of M/s Roche (MHRA Approved).
	For generic drugs (me-too status)	AVENTRIAX 500mg IV Injection of M/s Sanofi Aventis
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of ceftriaxone sodium is present in USP. The firm has submitted details of nomenclature, structure, general properties,

		solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (011302001, 011302002, 011302003)
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established with comparator product Aventrix 500mg Injection by Sanofi Aventis Pharma by performing quality tests (Identification, assay, dissolution, uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/S Sinopharm Weiqida Pharmaceutical Co. Ltd., First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.		
API Lot No.	Q0121039028		
Description of Pack (Container closure system)	Transparent PVC tray Sealed with printed A.foil filled with Dry Sterile Powder ceftriaxone in clear glass vial One Ampoule of water for injection and aluminum Foil with embossed board unit carton UV coated. (1's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months	Accelerated: 6 months	
Frequency	Accelerated: 0, 2, 4, 6 (Months)	Real Time: 0, 3, 6 (Months)	
Batch No.	007	008	009
Batch Size	1200 Vials	1200 Vials	1200 Vials
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	09-06-2021	09-06-2021	09-06-2021
No. of Batches	03		

DOCUMENTS/DATA ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. SX20180229 issued by CFDA valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.0090/2021/ DRAP-CPS/1330 CD(I&E) dated 16-04-2021 wherein the permission to import different APIs ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. AHPAO505150 dated 04-05-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	Observations communicated	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Copies of drug substance specifications and analytical procedures were provided by drug substance manufacturer.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The submitted analytical method verification studies were performed by drug substance manufacturer. Method verification studies were not performed by drug product manufacturer.
3.	The tests for crystallinity and particulate matter are not performed by drug product manufacturer. The assay limit specified by drug substance manufacturer (>84.0%) is different from that specified by drug product manufacturer (NLT 79%). Justification is required.	Not submitted. Assay limit as specified by drug substance manufacturer > 84% is according to CP 2010 as provided by Sinopharm. While QC department of Alpenglow has followed USP 43 which specifies assay limit = NLT 79%.
4.	Provide COA of reference standard which is actually used in the analysis of drug substance.	Instead of providing CoA from drug substance manufacturer, the firm has provided CoA of working standard of FPP manufacturer.
5.	Submit master formulation including theoretical fill weight per vial.	The firm has provided theoretical fill weight of ceftriaxone sodium per vial.
6.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Not submitted
7.	Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.	Not submitted
8.	Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.	Not submitted

<table>
<tr><td>9.</td><td>Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.</td><td>The firm has provided testing method of ceftriaxone sodium raw material. The chromatographic conditions are different from USP.
<table>
<tr><th>Parameters</th><th>Submitted monograph</th><th>USP monograph</th></tr>
<tr><td>Column</td><td>4mm × 15cm packing L1</td><td>4.6-mm × 25-cm; 5-µm packing</td></tr>
<tr><td>Flow rate</td><td>2.0 ml/min</td><td>1.5 ml/min</td></tr>
<tr><td>Detector</td><td>270nm</td><td>UV 254 nm</td></tr>
<tr><td>Mobile phase</td><td>Tetraheptyl ammonium bromide in 400ml of acetonitrile</td><td>Tetradecyl ammonium bromide and tetraheptyl ammonium bromide in a mixture of 440 mL ofwater, 55 mL of Buffer, 5.0 mL of Solution C, and 500 mL of acetonitrile.</td></tr>
</table></td></tr>
<tr><td>10.</td><td>Provide standard and sample preparation method used in analytical method verification studies.</td><td>Not submitted.</td></tr>
<tr><td>11.</td><td>Specify the details of the accuracy and specificity test including the details of concertation of 80%, 100% and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies.</td><td>Not submitted.</td></tr>
<tr><td>12.</td><td>Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required.
Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. The peak area of standard solution concentration in analytical method verification studies is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately. Clarify the difference in peak areas.</td><td>The firm has submitted analytical method verification studies of drug product including specificity, accuracy and precision.

Not submitted.</td></tr>
<tr><td>13.</td><td>Provide COA of reference standard actually used in the analysis of drug product.</td><td>The firm has submitted COA of working standard from drug product manufacturer.</td></tr>
<tr><td>14.</td><td>• In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.
• The tests for water contents, constituted solution etc are not performed during stability studies since these tests are required to make assessment of the stability profile.</td><td>Not submitted

Not provided</td></tr>
</table>

	• Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. Reference of previous approval of applications with stability study data of the firm (if any).	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
15.	• Pharmaceutical equivalence of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted.	The firm has submitted pharmaceutical equivalence data against Rocephin 500mg IV injection (batch # 6121z31) by performing quality tests.

Decision: Deferred for following:

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification studies for testing of ceftriaxone sodium as per USP recommendations.
2.	Performance of tests of crystallinity and particulate matter by drug product manufacturer.	The tests were performed as per USP monograph. The crystallinity test was performed however, particulate matter test was performed for product.
3.	Justify the difference in assay limit specified by drug substance manufacturer (>84.0%) and drug product manufacturer (NLT 79%).	The drug substance manufacturer follows USP as well as Chinese pharmacopoeia monograph for ceftriaxone sodium, so claims the assay limit > 84%. While being the drug product manufacturer we have followed the USP monograph for ceftriaxone and USP specifies the limit of NLT 79.5%.
4.	Justify the chromatographic conditions in the submitted analytical procedures which are different from USP monograph.	The chromatographic conditions specified in analytical procedure are as per older version of USP 29. We have updated the specifications according to the latest version of USP. The product was tested in accordance with updated conditions and the results were found satisfactory and within limits.
5.	Submit master formulation including details of potency adjustment as per assay results on certificate of analysis.	The firm has submitted master formulation with calculations of fill weight as per assay result on certificate of analysis.
6.	Performance of compatibility studies for the dry powder for injections as per the instructions provided in individual label of the drug product.	Sterile water for injection is the recommended diluent for intravenous injection of ceftriaxone sodium prior to administration. The results of compatibility and reconstitution studies are provided.
7.	Provide standard and sample preparation method used in analytical method verification studies.	The firm has provided methods for standard and sample preparation used in method verification studies of drug product.
8.	Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	The firm has specified the concentrations of 80% (0.24mg/ml), 100% (0.30mg/ml) and 120% (0.36mg/ml) used in accuracy studies. Moreover, details of blank solution, placebo and sample solution were provided in specificity study.
9.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted method verification studies of drug product as per the USP recommendation.
10.	Clarify the difference in peak area for standard solution concentration in analytical method verification studies which is approximately 6472293 while the peak area of the standard	The reason for area difference was that in verification studies the injection volume was different. The change in injection volume was a deviation to USP method, so the method was re-

	solution of same concentration in stability studies is 436282 approximately.	verified using standard USP method without any deviation. The area obtained was approximately same as that in stability studies.
11.	Provide COA of reference standard actually used in the analysis of drug product.	COA of USP primary reference standard with lot no: H0J296 has been provided.
12.	Provide in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	The product is recommended to be used instantly after reconstitution, however if stored in refrigerator the product can be used in 24 h. So 24 h in-use stability study was performed.
13.	Performance of tests for water contents, constituted solution etc during stability studies since these tests are required to make assessment of the stability profile.	The firm has submitted that the constituted solution was checked at every point of stability study since the assay is performed after reconstituting the injection. After reconstitution and before assay the injection was checked for particulate matter or other foreign matter. The revised stability summary sheets were provided.
14.	Evidence of procurement of API with approval from DRAP.	The firm has submitted copy of invoice specifying import of Ceftriaxone sodium 50Kg (Batch # Q012102085) attested by Assistant Director (I & E), Peshawar dated 16-04-2021.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will submit results of pharmaceutical equivalence against the innovator's product before issuance of Registration Letter.**

463.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5235 Dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	CIAXON 1 gm IM Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as sodium ……. 1 gm
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, Third-generation cephalosporins
	Reference to Finished product specifications	USP
	Proposed Pack size	1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 1gm IM Injection of M/s Hoffman LA Roche (USFDA Approved).
	For generic drugs (me-too status)	AVENTRIAX 1 gm IM injection
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of ceftriaxone sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (011302001, 011302002, 011302003)
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Aventrix 1g Injection by Sanofi Aventis Pharma by performing quality tests (Identification, assay, dissolution, uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.
STABILITY STUDY DATA		

Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd.		
API Lot No.	Q0121039028		
Description of Pack (Container closure system)	Transparent PVC tray Sealed with printed A.foil filled with Dry Sterile Powder ceftriaxone in clear glass vial One Ampoule of water for injection and aluminum Foil with embossed board unit carton UV coated. (1's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	016	017	018
Batch Size	750 Vials	750 Vials	750 Vials
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	09-06-2021	09-06-2021	09-06-2021
No. of Batches	03		

DOCUMENTS/DATA ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SX20180229 issued by CFDA valid till 05/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.0090/2021/DRAP-CPS/1330 CD(I&E) dated 16/04/2021 is submitted wherein the permission to import different APIs ceftriaxone as sodium for the purpose of test/analysis and stability studies is granted. AHPAO505150 dated 04/05/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	Observations communicated	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Copies of drug substance specifications and analytical procedures were provided by drug substance manufacturer.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The submitted analytical method verification studies were performed by drug substance manufacturer. Method verification studies were not performed by drug product manufacturer.

3.	The tests for crystallinity and particulate matter are not performed by drug product manufacturer. The assay limit specified by drug substance manufacturer (>84.0%) is different from that specified by drug product manufacturer (NLT 79%). Justification is required.	Not submitted. Assay limit as specified by drug substance manufacturer > 84% is according to CP 2010 as provided by Sinopharm. While QC department of Alpenglow has followed USP 43 which specifies assay limit = NLT 79%.
4.	Provide COA of reference standard which is actually used in the analysis of drug substance.	Instead of providing CoA from drug substance manufacturer, the firm has provided CoA of working standard of FPP manufacturer.
5.	Submit master formulation including theoretical fill weight per vial.	The firm has provided theoretical fill weight of ceftriaxone sodium per vial.
6.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Not submitted
7.	Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.	Not submitted
8.	Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.	Not submitted
9.	Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.	The firm has provided detailed testing method for the applied drug product.
10.	Provide standard and sample preparation method used in analytical method verification studies.	Not submitted.
11.	Specify the details of the accuracy and specificity test including the details of concertation of 80%, 100% and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies.	Not submitted
12.	Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required. Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. The peak area of standard solution concentration in analytical method verification studies is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately. Clarify the difference in peak areas.	The firm has submitted analytical method verification studies of drug product including specificity, accuracy and precision. Not submitted.
13.	Provide COA of reference standard actually used in the analysis of drug product.	The firm has submitted COA of working standard from drug product manufacturer.
14.	• In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided. • The tests for water contents, constituted solution etc are not performed	Not submitted Not provided

	during stability studies since these tests are required to make assessment of the stability profile. • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. Reference of previous approval of applications with stability study data of the firm (if any).	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
15.	• Pharmaceutical equivalence of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted.	The firm has submitted pharmaceutical equivalence data against Rocephin 1g IM injection (batch # 6121z015) by performing quality tests.

Deferred for submission of following

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification studies for testing of ceftriaxone sodium as per USP recommendations.
2.	Performance of tests of crystallinity and particulate matter by drug product manufacturer.	The tests were performed as per USP monograph. The crystallinity test was performed however, particulate matter test was performed for product.
3.	Justify the difference in assay limit specified by drug substance manufacturer (>84.0%) and drug product manufacturer (NLT 79%).	The drug substance manufacturer follows USP as well as Chinese pharmacopoeia monograph for ceftriaxone sodium, so claims the assay limit > 84%. While being the drug product manufacturer we have followed the USP monograph for ceftriaxone and USP specifies the limit of NLT 79.5%.
4.	Justify the chromatographic conditions in the submitted analytical procedures which are different from USP monograph.	The chromatographic conditions specified in analytical procedure are as per older version of USP 29. We have updated the specifications according to the latest version of USP. The product was tested in accordance with updated conditions and the results were found satisfactory and within limits.
5.	Submit master formulation including details of potency adjustment as per assay results on certificate of analysis.	The firm has submitted master formulation with calculations of fill weight as per assay result on certificate of analysis.
6.	Performance of compatibility studies for the dry powder for injections as per the instructions provided in individual label of the drug product.	Sterile lignocaine for injection is the recommended diluent for IM injection of ceftriaxone sodium prior to administration. The results of compatibility and reconstitution studies are provided.
7.	Provide standard and sample preparation method used in analytical method verification studies.	The firm has provided methods for standard and sample preparation used in method verification studies of drug product.
8.	Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	The firm has specified the concentrations of 80% (0.24mg/ml), 100% (0.30mg/ml) and 120% (0.36mg/ml) used in accuracy studies. Moreover, details of blank solution, placebo and sample solution were provided specificity study.

9.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted method verification studies of drug product as per the USP recommendation.
10.	Clarify the difference in peak area for standard solution concentration in analytical method verification studies which is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately.	The reason for area difference was that in verification studies the injection volume was different. The change in injection volume was a deviation to USP method, so the method was re-verified using standard USP method without any deviation. The area obtained was approximately same as that in stability studies.
11.	Provide COA of reference standard actually used in the analysis of drug product.	COA of USP primary reference standard with lot no: H0J296 has been provided.
12.	Provide in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	The product is recommended to be used instantly after reconstitution, however if stored in refrigerator the product can be used in 24 h. So 24 h in-use stability study was performed.
13.	Performance of tests for water contents, constituted solution etc during stability studies since these tests are required to make assessment of the stability profile.	The firm has submitted that the constituted solution was checked at every point of stability study since the assay is performed after reconstituting the injection. After reconstitution and before assay the injection was checked for particulate matter or other foreign matter. The revised stability summary sheets were provided.
14.	Evidence of procurement of API with approval from DRAP.	The firm has submitted copy of invoice specifying import of Ceftriaxone sodium 50Kg (Batch # Q012102085) attested by Assistant Director (I & E), Peshawar dated 16-04-2021.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will submit results of pharmaceutical equivalence against the innovator's product before issuance of Registration Letter.**

464.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5236 Dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	CIAXON 1 gm IV Injection

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as Sodium……1 gm
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 1gm IV Injection of M/s Hoffman LA Roche (USFDA Approved).
	For generic drugs (me-too status)	AVENTRIAX 1 gm IV Injection
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China Tel: 0352-7698888 Fax: 0352-7695555 Post Code: 037300 E-mail: yyueying@sohu.com
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ceftrioxone Sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (011302001, 011302002, 011302003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Aventrix 250mg Injection by Sanofi Aventis Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/S Sinopharm Weiqida Pharmaceutical Co., Ltd.		
API Lot No.	Q0121039028		
Description of Pack (Container closure system)	Transparent PVC tray Sealed with printed A.foil filled with Dry Sterile Powder ceftriaxone in clear glass vial One Ampoule of water for injection and aluminum Foil with embossed board unit carton UV coated. (1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	013	014	015
Batch Size	750 Vials	750 Vials	750 Vials
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	09-06-2021	09-06-2021	09-06-2021
No. of Batches	03		

DOCUMENTS/DATA ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SX20180229 issued by CFDA valid till 05/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.0090/2021/DRAP-CPS/1330 CD(I&E) dated 16/04/2021 is submitted wherein the permission to import different APIs ceftriaxone as sodium for the purpose of test/analysis and stability studies is granted. AHPAO505150 dated 04/05/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	Observations communicated	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical	Copies of drug substance specifications and analytical procedures were provided by drug substance manufacturer.

	Ingredient by both Drug substance & Drug Product manufacturer is required.	
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The submitted analytical method verification studies were performed by drug substance manufacturer. Method verification studies were not performed by drug product manufacturer.
3.	The tests for crystallinity and particulate matter are not performed by drug product manufacturer. The assay limit specified by drug substance manufacturer (>84.0%) is different from that specified by drug product manufacturer (NLT 79%). Justification is required.	Not submitted. Assay limit as specified by drug substance manufacturer > 84% is according to CP 2010 as provided by Sinopharm. While QC department of Alpenglow has followed USP 43 which specifies assay limit = NLT 79%.
4.	Provide COA of reference standard which is actually used in the analysis of drug substance.	Instead of providing CoA from drug substance manufacturer, the firm has provided CoA of working standard of FPP manufacturer.
5.	Submit master formulation including theoretical fill weight per vial.	The firm has provided theoretical fill weight of ceftriaxone sodium per vial.
6.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Not submitted
7.	Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.	Not submitted
8.	Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.	Not submitted
9.	Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.	The firm has provided detailed testing method for the applied drug product.
10.	Provide standard and sample preparation method used in analytical method verification studies.	Not submitted.
11.	Specify the details of the accuracy and specificity test including the details of concertation of 80%, 100% and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies.	Not submitted
12.	Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required. Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. The peak area of standard solution concentration in analytical method verification studies is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately. Clarify the difference in peak areas.	The firm has submitted analytical method verification studies of drug product including specificity, accuracy and precision. Not submitted.
13.	Provide COA of reference standard actually used in the analysis of drug product.	The firm has submitted COA of working standard from drug product manufacturer.
14.	• In-use studies for drug products which are to be reconstituted before use, along with proposed	Not submitted

	in-use storage statement and in-use shelf-life shall be provided. • The tests for water contents, constituted solution etc are not performed during stability studies since these tests are required to make assessment of the stability profile. • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. Reference of previous approval of applications with stability study data of the firm (if any).	Not provided The firm has submitted that our current HPLC system is not 21 CFR compliant, we will try to upgrade our system as soon as possible.
	• Pharmaceutical equivalence of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted.	The firm has submitted pharmaceutical equivalence data against Rocephin 1g IV injection (batch # 6121z015) by performing quality tests.

Deferred for submission of following:

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification studies for testing of ceftriaxone sodium as per USP recommendations.
2.	Performance of tests of crystallinity and particulate matter by drug product manufacturer.	The tests were performed as per USP monograph. The crystallinity test was performed however, particulate matter test was performed for product.
3.	Justify the difference in assay limit specified by drug substance manufacturer (>84.0%) and drug product manufacturer (NLT 79%).	The drug substance manufacturer follows USP as well as Chinese pharmacopoeia monograph for ceftriaxone sodium, so claims the assay limit > 84%. While being the drug product manufacturer we have followed the USP monograph for ceftriaxone and USP specifies the limit of NLT 79.5%.
4.	Justify the chromatographic conditions in the submitted analytical procedures which are different from USP monograph.	The chromatographic conditions specified in analytical procedure are as per older version of USP 29. We have updated the specifications according to the latest version of USP. The product was tested in accordance with updated conditions and the results were found satisfactory and within limits.
5.	Submit master formulation including details of potency adjustment as per assay results on certificate of analysis.	The firm has submitted master formulation with calculations of fill weight as per assay result on certificate of analysis.
6.	Performance of compatibility studies for the dry powder for injections as per the instructions provided in individual label of the drug product.	Sterile water for injection is the recommended diluent for intravenous injection of ceftriaxone sodium prior to administration. The results of compatibility and reconstitution studies are provided.
7.	Provide standard and sample preparation method used in analytical method verification studies.	The firm has provided methods for standard and sample preparation used in method verification studies of drug product.
8.	Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	The firm has specified the concentrations of 80% (0.24mg/ml), 100% (0.30mg/ml) and 120% (0.36mg/ml) used in accuracy studies. Moreover, details of blank solution, placebo and sample solution were provided specificity study.

9.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted method verification studies of drug product as per the USP recommendation.
10.	Clarify the difference in peak area for standard solution concentration in analytical method verification studies which is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately.	The reason for area difference was that in verification studies the injection volume was different. The change in injection volume was a deviation to USP method, so the method was re-verified using standard USP method without any deviation. The area obtained was approximately same as that in stability studies.
11.	Provide COA of reference standard actually used in the analysis of drug product.	COA of USP primary reference standard with lot no: H0J296 has been provided.
12.	Provide in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	The product is recommended to be used instantly after reconstitution, however if stored in refrigerator the product can be used in 24 h. So 24 h in-use stability study was performed.
13.	Performance of tests for water contents, constituted solution etc during stability studies since these tests are required to make assessment of the stability profile.	The firm has submitted that the constituted solution was checked at every point of stability study since the assay is performed after reconstituting the injection. After reconstitution and before assay, the injection was checked for particulate matter or other foreign matter. The revised stability summary sheets were provided.
14.	Evidence of procurement of API with approval from DRAP.	The firm has submitted copy of invoice specifying import of Ceftriaxone sodium 50Kg (Batch # Q012102085) attested by Assistant Director (I & E), Peshawar dated 16-04-2021.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will submit results of pharmaceutical equivalence against the innovator's product before issuance of Registration Letter.**

Deferred cases (New License):

The Central Licensing Board in its 271st meeting held on 12th September, 2019 has considered and approved the grant of Drug Manufacturing License to M/s Himark Laboratories Pvt Ltd. Plot 37-A, Sundar Industrial Estate, Lahore by way of Formulation vide approval letter No. F. 1-67/2005-Lic dated 29th Sep, 2019 with following (06) sections.

Name of Section	**Considered till 313th RB meeting**		**Freshly applied**	
	No of molecules	**No of products**	**No of molecules**	**No of products**
Tablet (General & General Antibiotic) Section	2	5	2	2
Capsule (General & General Antibiotic) Section	4	9	1	2
Dry Powder Suspension (General & General Antibiotic) Section	3	5	1	1
Sachet (General) Section	-	-	1	1
Oral Liquid Syrup Section	2	3	2	3
Cream/Ointment (General) Section	-	-	-	-

465.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.

	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.30582; Dated: 08-11-2021
	Details of fee submitted	PKR 20,000/-: Dated 31-12-2020 PKR 10,000/- Duplicate challan date not mentioned
	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Capsule (General & General Antibiotic) section approved.
	The proposed proprietary name / brand name	Dicmark 50 mg DR capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Diclofenac sodium (as Diclofenac sodium EC Pellets 24%)……50 mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	2 ×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Deflamat 50 mg – Kapseln, Astellas Pharma GmbH Linzer Straße 221/E02 1140 Vienna Austria, AGES (Austria) Approved.
	For generic drugs (me-too status)	Phlogin 50 mg cap (Enteric coated pellets) by M/s Brookes Pharma, Reg. No. 009128
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, water determination, Assay and tests for total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(DE-161, DE-469, DE-597)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Phlogin 50 mg capsule** by **Brookes Pharma** by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	DE706		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (2 x 10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-49	T-50	T-51
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	16-03-2020	16-03-2020	16-03-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
466.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
467.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad. It is valid till 10-02-2022.
468.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase of Diclofenac sodium EC pellets 24 % (Batch # DE706, 1Kg) dated 11-03-2020.
469.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches have been submitted by UV method alongwith respective documents like COA, summary data sheets.

470.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted that testing of Dicmark 50mg DR capsule has been performed on UV spectrophotometer.
471.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted.

Sr. No.	Observations	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. However, relevant chromatograms of tested parameters were not provided.
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	The firm has provided results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during stability studies, along with certificate of analysis (CoA) of the same batch.
4.	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests of the developed formulation and the innovator product shall be submitted and discussed.	The firm has submitted pharmaceutical equivalence data of developed formulation (batch # T-49) against comparator brand Phlogin DR 50mg Capsule (Batch # 09519) of M/s Brookes pharma. Reference of WHO technical report series No. 902, 2002 has been given to justify the selection of market brand leader if innovator is not available.
5.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	The firm has provided details of applicant and comparator product.
6.	Justification is required for performing assay testing by UV method instead of HPLC method.	Dicmark 50mg DR Capsule is a non-compendial product. We have performed method validation on UV spectrophotometer, hence we performed assay testing by UV method.
7.	Justification is required for setting dissolution limit in phosphate buffer stage as NLT 70% in 45 min which is different from that mentioned in Stability study protocol i.e., NLT 80% in 45 min.	The firm has submitted that 70% in 45min is a typographic mistake. Actual limit is NLT 80% in 45 min in phosphate buffer in Dissolution test as written in stability protocol.
8.	Analytical method verification of drug product includes performance of test of Detection limit and Quantitation limit by HPLC method. Clarification is required.	The firm has submitted revised reports of performance of test of Detection limit and Quantitation limit by UV method.
9.	Documents for the procurement of the API including purchase invoice from M/s M/s Vision Pharmaceuticals (Pvt.) Ltd.	The firm has submitted copy of invoice for the purchase of Diclofenac sodium EC pellets 24 % (Batch # DE706, 1Kg) dated 11-03-2020.
10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted that testing of Dicmark 50mg DR capsule has been performed on UV spectrophotometer.

11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted.

Deferred for submission of following:

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method validation reports of drug substance by performing precision, linearity, accuracy and specificity parameters.
2.	Justification of adopting UV-visible spectrophotometric method for assay testing of applied formulation.	Dicmark 50mg DR Capsule is a non-pharmacopoeial product. The UV method for assay testing was adopted because BP adopts UV method for Diclofenac sodium prolonged release capsule and moreover manufacturer of API (i.e. Vision Pharma) also uses UV method for assay testing.
3.	Performance of pharmaceutical equivalence and CDP studies with innovator/reference product.	The firm has submitted pharmaceutical equivalence data of developed formulation (batch # T-49) against comparator brand Phlogin DR 50mg Capsule (Batch # 09519) of M/s Brookes pharma. Reference of WHO technical report series No. 902, 2002 has been given to justify the selection of market brand leader if innovator is not available.
4.	Analytical method verification reports of drug product performed by drug product manufacturer.	Analytical method validation reports of drug product have been provided by performing precision, linearity, accuracy and specificity parameters.

Decision: Approved.

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

472.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019. Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission	Dy. No.30581: Dated 08-11-2021
	Details of fee submitted	PKR 20,000/-: Dated 20-05-2021 PKR 10,000/-: Duplicate challan date not mentioned

	The proposed proprietary name / brand name	Lorak 10 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Loratadine .....10 mg
	Pharmaceutical form of applied drug	White to off white round uncoated tablet
	Pharmacotherapeutic Group of (API)	Antihistamines –H1 antagonists
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1 ×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarityn Allergy 10mg Tablets by M/s UCB Pharma, (MHRA Approved).
	For generic drugs (me-too status)	Softin 10 mg Tablet by M/s Werrick Pharmaceuticals, (Reg # 012026)
	Name and address of API manufacturer.	M/s. Vasudha Pharma Chem Limited., 78/A, VENGALRAO NAGAR, HYDERABAD –500038, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months (BLRD/001/11, BLRD/002/11, BLRD/003/11)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the brand leader that is ***Tirlor Tablet of Novartis Pharma*** by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is ***Tirlor Tablet*** by ***Novartis Pharma*** in Acid media (pH 1.0-1.2), phosphate buffer (pH 4.5 & pH 6.8).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Vasudha Pharma Chem Limited., 78/A, Vengalrao Nagar, Hyderabad – 500038, India.		
API Lot No.	BLRD/1911023		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-28	T-29	T-30
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	27-01-2020	27-01-2020	27-01-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. L. Dis. No. 5741/P&B/2001 issued by Drugs Control Administration (Govt. of Andhra Pradesh) India valid till 20-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/ DRAP-AD-CD(I&E) dated 26-12-2019 is submitted wherein the permission to import different APIs Loratadine for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted stability data supported by respective documents like chromatograms, and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of data logger sheets for temperature and humidity monitoring of stability chambers (real time and accelerated.

Sr. No.	Observations	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameter were not provided.
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.	The firm has provided results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during stability studies, along with certificate of analysis (CoA) of the same batch.
4.	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests of the developed formulation and the innovator product shall be submitted and discussed.	Pharmaceutical equivalence has been established against the brand leader that is ***Tirlor Tablet of Novartis Pharma*** by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
5.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	Applicant batch no.: Lorak 10 mg Tablet = T-28 Comparator batch no.: Tirlor 10mg tablet of M/s Novartis pharma = 102
6.	Submit date of analysis of pharmaceutical equivalence and comparative dissolution profile alongwith chromatograms / spectra.	The firm has stated date of analysis 27-01-2020 and relevant chromatograms / spectra were not provided.
7.	Control of excipients is missing.	The firm has submitted that excipients used in the formulation are of pharmacopoeial grade and we are using BP specifications.
8.	Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required.	The firm has not submitted results for specificity test.
9.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	The firm has submitted raw data sheets for the assay test.
10.	The submitted chromatograms in stability studies (3.2.P.8) do not differentiate between real time or accelerated stability studies time points of different batches.	The firm has not submitted chromatograms of all time points of real time and accelerated stability studies.
11.	Submit copies of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMRs for three batches.
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated.

Deferred for submission of following:

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product	The firm has submitted analytical method verification reports of drug substance by

	manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	performing precision, linearity, accuracy, specificity and system suitability studies.
2.	HPLC chromatograms of all time points of real time and accelerated stability studies.	The firm has provided HPLC chromatograms of real time and accelerated stability studies for 0, 3 and 6-month time point.
3.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted analytical method verification reports of drug product by performing precision, linearity, accuracy, specificity and system suitability studies.

Decision: Approved.

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

473.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Oral Liquid Syrup section approved.
	Dy. No. and date of submission	Dy. No. 30580: Dated 08-11-2021
	Details of fee submitted	PKR 20,000/-: Dated 20-05-2021 PKR 10,000/-: Duplicate challan date not mentioned
	The proposed proprietary name / brand name	Lorak 5 mg / 5 mL oral solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml contains: Loratadine….....5 mg
	Pharmaceutical form of applied drug	Transparent to yellowish sweet taste orange flavor oral solution
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1 × 60 mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Loratadine 5 mg / 5 ml syrup by M/s Generics [UK] Limited t/a Mylan, MHRA Approved.
	For generic drugs (me-too status)	Lorel 1mg/mL Syrup by M/s Standpharm (Reg # 020951)
	Name and address of API manufacturer.	M/s Vasudha Pharma Chem Limited.,78/A, VENGALRAO NAGAR, HYDERABAD – 500038, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties,

		solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Loratadine is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months (BLRD/001/11, BLRD/002/11, BLRD/003/11)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the brand leader that is Lorel Syrup by Standpharm by performing quality tests (Identification, Assay, pH, microbial enumeration tests & tests for specified micro-organisms). CDP – Not applicable
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Vasudha Pharma Chem Limited., 78/A, Vengalrao Nagar, Hyderabad – 500038, INDIA		
API Lot No.	BLRD/1911023		
Description of Pack (Container closure system)	Clear & transparent solution with sweet taste & tutti-fruiti flavor filled in amber glass bottles in packs of 60 mL, further packed in unit carton provided with leaflet insert and a spoon.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-31	T-32	T-33

Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	12-02-2020	12-02-2020	12-02-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. 5741/P&B/2001 issued by Drugs Control Administration, Government of Andhra Pradesh, India valid till 20-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/ DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs Loratadine for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted stability data supported by respective documents like chromatograms, and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of data logger sheets for temperature and humidity monitoring of stability chambers (real time and accelerated.

Sr. No.	**Observations**	**Response by the firm**
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameter were not provided.
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.	The firm has provided results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during stability studies, along with certificate of analysis (CoA) of the same batch.
4.	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests of the developed formulation and the innovator product shall be submitted and discussed.	The firm has performed pharmaceutical equivalence studies with comparator product. The details are below:
5.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	Applicant batch no.: Lorak 5 mg /5ml Oral solution = T-31 Comparator batch no.: Lorel 5mg /5ml oral solution of M/s StandPharma = 004G
6.	Submit date of analysis of pharmaceutical equivalence and comparative dissolution profile alongwith chromatograms / spectra.	The firm has stated date of analysis 12-02-2020, however relevant chromatograms / spectra were not provided.

7.	Control of excipients is missing.	The firm has submitted that excipients used in the formulation are of pharmacopoeial grade and we are using BP specifications.
8.	Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required.	The firm has not submitted results for specificity test.
9.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	The firm has not submitted analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) for drug product.
10.	The submitted chromatograms in stability studies (3.2.P.8) do not differentiate between real time or accelerated stability studies time points of different batches.	The firm has not submitted chromatograms of all time points of real time and accelerated stability studies.
11.	Submit copies of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMRs for three batches.
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated.

Deferred for submission of following:

Sr. No.	**Decision of 316th meeting of RB**	**Response by the firm**
4.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification reports of drug substance by performing precision, linearity, accuracy, specificity and system suitability studies.
5.	HPLC chromatograms of all time points of real time and accelerated stability studies.	The firm has submitted HPLC chromatograms of real time and accelerated stability studies for 0, 3 and 6-month time point.
6.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted analytical method verification reports of drug substance by performing precision, linearity, accuracy, specificity and system suitability studies.

Decision: Approved.

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

474.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Oral Liquid Syrup section approved.
	Dy. No. and date of submission	Dy. No. 30579: Dated: 08-11-2021
	Details of fee submitted	PKR 20,000/-: Dated 20-02-2021 PKR 10,000/-: Date not mentioned
	The proposed proprietary name / brand name	Hitran Paediatric Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 mL suspension contains: Trimethprim.....40 mg Sulfamethoxazole.....200 mg
	Pharmaceutical form of applied drug	Clear sweet strawberry flavored homogeneous oral suspension filled in amber glass bottle sealed with aluminium cap and packed in printed unit cartons.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1 × 50 mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bactrim Suspension by M/s Sun Pharm industries, (USFDA Approved).
	For generic drugs (me-too status)	Septran Paediatric Suspension by M/s GSK Pharma (Reg. No. 000384)
	Name and address of API manufacturer.	M/s Shouguang Fukang Pharmaceutical company Ltd., North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Trimethoprim:** The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Sulfamethoxazole:** The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches of Trimethoprim: (201103504, 201103505, 201103506) Batches of Sulfamethoxazole: Accelerated: (200604001, 200604002, 200604003) Real Time: (2007706001, 2007706002, 2007706003)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the brand leader that is Septran Paediatric Suspension by GSK Pharma by performing quality tests (Identification, Assay, pH, Deliverable volume). CDP – Not applicable
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shouguang Fukang Pharmaceutical company Ltd., North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, People's Republic of China.		
API Lot No.	Trimethoprim: A-50112007004-0500 Sulfamethoxazole: A-50212005029		
Description of Pack (Container closure system)	***Hitran Paediatric Suspension*** is filled in amber glass bottle sealed with pilfer proof aluminium cap and packed in a box board unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-88	T-89	T-90
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	26-08-2020	26-08-2020	26-08-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (Certificate # 20190888) for M/s Shouguang Fukang Pharmaceutical Co. Ltd. issued by China Food and Drug Administration valid till 12-03-2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD (I&E) dated 26-12-2019 wherein the permission to import different APIs Trimethoprim & Sulfamethoxazole for the purpose of test/analysis and stability studies is granted. Invoice for the purchase of materials is not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith raw data sheets, COA, summary data sheets. Relevant UV scans were not provided.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The testing of applied product is performed on UV spectrophotometer and audit trail reports not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

The firm has claimed BP specifications however, the product is also present in USP monograph.

Sr. No.	Observations	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Submit evidence of equipments required for potentiometric titration and electrometric titration required for analysis of trimethoprim and sulfamethoxazole, respectively.	The firm has not provided evidence of availability of potentiometer.
3.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameters were not provided.
4.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from drug substance manufacturer.	The firm has provided results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during stability studies, along with certificate of analysis (CoA) of the same batch.
5.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	Applicant batch no.: Hitran Paediatric suspension = T-88 Comparator batch no.: Septran paediatric Suspension = KR5B
6.	Discussion of microbiological attributes of the Drug Product (e.g. preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	The firm has not submitted preservative effectiveness studies as recommended by Pharmacopoeia.
7.	Control of excipients is missing.	The firm has submitted that excipients used in the formulation are of pharmacopoeial grade and we are using BP specifications and analytical methods for all tests except Flavor Banana & Flavor Vanilla for which analytical procedures are attached.
8.	Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required.	The firm has not submitted results for specificity test.

9.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	The firm has not submitted analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) for drug product.
10.	Provide raw data sheets wherein details of sample solution preparation and standard solution and calculation formula for the assay test shall be mentioned	The firm has submitted raw data sheets for the assay test.
11.	Submitted DHL invoice is for M/s Scilife Pharma (Pvt.) Ltd. Clarification is required.	The firm has submitted that M/s Scilife Pharma (pvt.) Ltd was written mistakenly by DHL. The materials were directly delivered to our plant.
12.	Supportive documents like chromatograms / spectra are not submitted. Clarification is required.	The testing of Hitran Pediatric Suspension has been performed on UV-Spectrophotometer. However, relevant UV scans have not been submitted.
13.	Submit copies of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMRs for three batches.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated.

Deferred for submission of following:

Sr. No.	**Decision of 316th meeting of RB**	**Response by the firm**
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification reports for both sulphamethoxazole and trimethoprim by performing precision, linearity, accuracy, specificity.
2.	Preservative effectiveness studies performed as per recommendations of pharmacopoeia.	The firm has submitted performance of microbiological attributes of the drug product.
3.	Evidence of availability potentiometer including purchase invoice and IQ, OQ, PQ of the equipment.	Copy of invoice for the purchase of potentiometric titrator (Model # HI901) is attached. The firm has submitted installation qualification and operational qualification of potentiometer.
4.	Analytical method verification reports of drug product performed by drug product manufacturer.	The firm has submitted analytical method verification reports of drug product by performing precision, linearity, accuracy, specificity.
5.	Relevant UV spectra for assay testing as recommended by the BP monograph of applied formulation.	Our UV-spectrophotometer (Insmark 300/2) was not software base due to which prints cannot be taken. Now we have purchased new software of UV-spectrophotometer with print option. Now the firm has submitted UV spectra of dissolution testing of stability batches.
6.	Evidence of procurement of drug substance with approval from DRAP.	The firm has submitted copy of invoice specifying import of Sulphamethoxazole (2.0Kg) and Trimethoprim (0.5 Kg) attested by Assistant Director (I & E) dated 03-08-2020.

Decision: Approved.

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

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
475.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019 Oral Liquid Syrup section approved.
	Dy. No. and date of submission	Dy. No. 30578: Dated 08-11-2021
	Details of fee submitted	PKR 20,000/-: Dated 20-05-2021 PKR 10,000/-: Duplicate challan date not mentioned
	The proposed proprietary name / brand name	Hitran DS Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 mL suspension contains: Trimethprim .....80 mg Sulfamethoxazole .....400 mg
	Pharmaceutical form of applied drug	Clear sweet strawberry flavored homogeneous oral suspension filled in amber glass bottle sealed with aluminium cap and packed in printed unit cartons along with a patient information leaflet.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1 × 50 mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulfatrim Suspension by M/s Pharm Assoc, (USFDA Approved).
	For generic drugs (me-too status)	Septran DS Suspension by M/s GSK Pharma (Reg # 008752)
	Name and address of API manufacturer.	M/s Shouguang Fukang Pharmaceutical company Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, People's Republic of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	Official monograph of Trimethoprim and Sulfamethoxazole is present in BP. **Trimethoprim:** The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances, impurity K, heavy metals, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **Sulfamethoxazole:** The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances (impurities A, C, D, E) & impurity B, impurity F, unspecified impurities and total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches of Trimethoprim: (201103504,201103505, 201103506) Batches of Sulfamethoxazole: Accelerated: (200604001,200604002, 200604003 Real Time: (2007706001, 2007706002, 2007706003)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Septran DS Suspension by GSK Pharma by performing quality tests (Identification, Assay, pH, Uniformity of dosage unit). CDP – Not applicable
	Analytical method validation/verification of product	Analytical method verification reports have not been submitted including linearity, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Shouguang Fukang Pharmaceutical company Ltd., North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, People's Republic of China
API Lot No.	Trimethoprim: A-50112007004-0500

	Sulfamethoxazole: A-50212005029		
Description of Pack (Container closure system)	***Hitran DS Suspension*** is filled in amber glass bottle sealed with pilfer proof aluminium cap and packed in a in box board unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-91	T-92	T-93
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	27-08-2020	27-08-2020	27-08-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (Certificate # 20190888) for M/s Shouguang Fukang Pharmaceutical Co. Ltd. issued by China Food and Drug Administration valid till 12-03-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD (I&E) dated 26-12-2019 wherein the permission to import different APIs Trimethoprim & Sulfamethoxazole for the purpose of test/analysis and stability studies is granted. Invoice for the purchase of materials is not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith raw data sheets, COA, summary data sheets. Relevant UV scans were not provided.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The testing of applied product is performed on UV spectrophotometer and audit trail reports not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

The firm has claimed BP specifications while the product is also present in available USP.
Evidence of approval of applied formulation in reference regulatory authority could not be confirmed.

Sr. No.	Observations	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Submit evidence of equipments required for potentiometric titration and electrometric titration required for analysis of trimethoprim and sulfamethoxazole, respectively.	The firm has not provided evidence of availability of potentiometer.

3.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameters were not provided.
4.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.	The firm has provided results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during stability studies, along with certificate of analysis (CoA) of the same batch.
5.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	<table><tr><td>Applicant batch no.</td><td>Comparator batch no.</td></tr><tr><td>Hitran DS suspension = T-88</td><td>Septran DS Suspension = HR8P</td></tr></table>
6.	Discussion of microbiological attributes of the Drug Product (e.g. preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	The firm has not submitted preservative effectiveness studies as recommended by Pharmacopoeia.
7.	Control of excipients is missing.	The firm has submitted that excipients used in the formulation are of pharmacopoeial grade and we are using BP specifications and analytical methods for all tests except Flavor Banana & Flavor Vanilla for which analytical procedures are attached.
8.	Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required.	The firm has not submitted results for specificity test.
9.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	The firm has not submitted analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) for drug product.
10.	Provide raw data sheets wherein details of sample solution preparation and standard solution and calculation formula for the assay test shall be mentioned	The firm has submitted raw data sheets for the assay test.
11.	Submitted DHL invoice is for M/s Scilife Pharma (Pvt.) Ltd. Clarification is required.	The firm has submitted that M/s Scilife Pharma (pvt.) Ltd was written mistakenly by DHL. The materials were directly delivered to our plant.
12.	Supportive documents like chromatograms / spectra are not submitted. Clarification is required.	The testing of Hitran DS Suspension has been performed on UV-Spectrophotometer. However, relevant UV scans have not been submitted.
13.	Submit copies of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMRs for three batches.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated.

Deferred for submission of following:

Sr. No.	**Decision of 316th meeting of RB**	**Response by the firm**

1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification reports for both sulphamethoxazole and trimethoprim by performing precision, linearity, accuracy, specificity.
2.	Preservative effectiveness studies performed as per recommendations of pharmacopoeia.	The firm has submitted performance of microbiological attributes of the drug product.
3.	Evidence of availability potentiometer including purchase invoice and IQ, OQ, PQ of the equipment.	Copy of invoice for the purchase of potentiometric titrator (Model # HI901) is attached. The firm has submitted installation qualification and operational qualification of potentiometer.
4.	Analytical method verification reports of drug product performed by drug product manufacturer.	Analytical method verification reports of drug product by performing precision, linearity, accuracy, specificity have been submitted.
5.	Relevant UV spectra for assay testing as recommended by the BP monograph of applied formulation.	Our UV-spectrophotometer (Insmark 300/2) was not software base due to which prints cannot be taken. Now we have purchased new software of UV-spectrophotometer with print option. Now the firm has submitted UV spectra of dissolution testing of stability batches.
6.	Evidence of procurement of drug substance with approval from DRAP.	The firm has submitted copy of invoice specifying import of Sulphamethoxazole (2.0Kg) and Trimethoprim (0.5 Kg) attested by Assistant Director (I & E) dated 03-08-2020.

Decision: Approved.

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

476.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Sachet (General) section approved.
	Dy. No. and date of submission	Dy. No. 24083: Dated: 01-09-2021
	Details of fee submitted	PKR 30,000/-: Dated 21-06-2021
	The proposed proprietary name / brand name	Oestolos 2 g Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Strontium Ranelate……..... 2 g
	Pharmaceutical form of applied drug	Granules in sachet pack
	Pharmacotherapeutic Group of (API)	Anti-osteoporosis

	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1 × 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Strontium ranelate Aristo 2 g granules for oral suspension by M/s Aristo Pharma GmbH Wallenroder Straße 8-10 13435 Berlin Germany, MHRA Approved.
	For generic drugs (me-too status)	ONITA SACHET by M/s PHARM-EVO (PVT) LTD, (Reg. No. 057746)
	Name and address of API manufacturer.	M/s Suntril Pharmaceuticals Pvt. Ltd., Plot # 219, Phase-1, HSIIDC, Alipur Tehsil Barwala District Panchkula (Haryana), India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances (unspecified and total impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (STRHB 170001, STRHB 170002, STRHB 170003)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Osstium sachet** by **Atco** Pharma by performing quality tests (Identification, Assay, pH, Uniformity of dosage unit & loss on Drying). CDP – Not applicable
	Analytical method validation/verification of product	Analytical method verification reports have not been submitted including linearity, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Suntril Pharmaceuticals Pvt. Ltd., Plot # 219, Phase-1, HSIIDC, Alipur Tehsil Barwala District Panchkula (Haryana), India.		
API Lot No.	STRHB200003		
Description of Pack (Container closure system)	Aluminium Foil, 1 × 7's		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-100	T-101	T-102
Batch Size	100 Sachet	100 Sachet	100 Sachet
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	22-10-2020	22-10-2020	22-10-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. 1/151-2 Drug-1-2019/7839 issued by Food and Drug Administration Haryana Panchkula (India) valid till 22-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No. 17133/2019/DRAP-AD-CD(I&E) dated 26-12-2019 is submitted wherein the permission to import different API Strontium Ranelate for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Sr. No.	Observations	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameter were not provided.

3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameters were not provided.
4.	The reference formulation states granules for oral suspension for applied formulation. Clarification is required in manufacturing process and process control whether granules will be prepared in-house or otherwise.	Granules are prepared in-house by sieving the materials from appropriate mesh.
5.	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests of the developed formulation and the innovator product shall be submitted and discussed.	The firm has submitted pharmaceutical equivalence with comparator product Osstium Sachet of M/s Atco Labs.
6.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	Applicant batch no.: Oestolos 2g Sachet = T-100 Comparator batch no.: Osstium Sachet = UJ006FM1
7.	Control of excipients is missing.	The firm has submitted that excipients used in the formulation are of pharmacopoeial grade and we are using BP specifications
8.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	The firm has not submitted analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) for drug product.
9.	Provide raw data sheets wherein details of sample solution preparation and standard solution and calculation formula for the assay test shall be mentioned	The firm has submitted raw data sheets for the assay test.
10.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	The firm has not submitted invoice for the procurement of drug substance.
11.	Justification is required for submission of single chromatogram as test result of each batch at different time intervals.	The firm has not submitted chromatograms for real time and accelerated stability studies at different time intervals. Instead, single chromatogram for each test interval is submitted.

Deferred for submission of following:

Sr. No.	**Decision of 316th meeting of RB**	**Response by the firm**
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification reports of strontium ranelate by performing precision, linearity, accuracy, specificity and system suitability studies.
2.	HPLC chromatograms of all time points of real time and accelerated stability studies.	The firm has submitted HPLC chromatograms of real time and accelerated stability studies for 0, 3 and 6-month time point.
3.	Analytical method verification reports of drug product performed by drug product manufacturer.	Analytical method verification reports of strontium ranelate by performing precision, linearity, accuracy, and specificity have been submitted.
4.	Evidence of procurement of drug substance with approval from DRAP.	The firm has submitted copy of letter No. 17133/2019/DRAP-AD-CD(I&E) dated 26-12-2019 is submitted wherein the permission to

		import different API Strontium Ranelate for the purpose of test/analysis and stability studies is granted. The firm submitted that material was directly received at the plant. Import invoice is attached specifying import of Strontium ranelate 0.70 Kg (batch # STRHB200003).
Decision: Deferred for submission of documents confirming import of API i.e, Goods declaration/ Airway bill/Courier receipt etc.		
477.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019. Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission	Dy. No. 24085 Dated: 01-09-2021
	Details of fee submitted	PKR 30,000/-: Dated 21/06/2021
	The proposed proprietary name / brand name	Trox 10 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Cetirizine Dihydrochloride…….. 10 mg
	Pharmaceutical form of applied drug	White to off white round shaped without any score film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1 × 10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zirtek Allergy Relief 10 mg film-coated tablets by M/s UCB Pharma, MHRA Approved.
	For generic drugs (me-too status)	Avec 10mg Tablet by M/s Platinum Pharma, (Reg # 025506)
	Name and address of API manufacturer.	M/s Supriya Life sciences Ltd., Mumbai, INDIA. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – Khed, District – Ratnagiri, Maharashtra, India 415 722.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (SLL/CTR/0309047, SLL/CTR/0309048, SLL/CTR/0309047).
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against that is **Zyrtec 10 mg Tab** by GSK Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is **Zyrtec 10 mg Tab** by GSK Pharma in acidic media (pH 1.2) & phosphate buffer (pH 4.5 & 6.8). The values for f_2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method verification reports have not been submitted including linearity, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Supriya Lifescience Ltd., Mumbai, INDIA. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – Khed, District – Ratnagiri, Maharashtra, India 415 722.		
API Lot No.	CTZ/083/20-21		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-94	T-95	T-96
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	15-10-2020	15-10-2020	15-10-2020
No. of Batches	03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/67649/2018/11/25185 issued by Food and Drug Administration India valid till 04-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 wherein the permission to import different APIs Cetirizine Dihydrochloride for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Sr. No.	**Observations**	**Response by the firm**
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameter were not provided.
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameters were not provided.
4.	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests of the developed formulation and the innovator product shall be submitted and discussed.	The firm has submitted pharmaceutical equivalence with comparator product Osstium Sachet of M/s Atco Labs.
5.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	Applicant batch no.: Trox 10mg Tab = T-94 Comparator batch no.: Zyrtec 10mg Tab = 354 E
6.	Control of excipients is missing.	The firm has submitted that excipients used in the formulation are of pharmacopoeial grade and we are using BP specifications

7.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	The firm has not submitted analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) for drug product.
8.	Provide raw data sheets wherein details of sample solution preparation and standard solution and calculation formula for the assay test shall be mentioned.	The firm has submitted raw data sheets for the assay test.
9.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	Not submitted.
10.	UV spectra of dissolution data are required to be provided.	Not submitted.
11.	Justification is required for submission of single chromatogram as test result for each batch at different time intervals.	The submitted chromatograms do not differentiate between real time or accelerated stability studies time points of different batches.

Deferred for submission of following:

Sr. No.	**Decision of 316th meeting of RB**	**Response by the firm**
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification reports of drug substance by performing precision, linearity, accuracy, specificity and system suitability studies.
2.	HPLC chromatograms of all time points of real time and accelerated stability studies.	The firm has submitted HPLC chromatograms of real time and accelerated stability studies for 0, 3 and 6-month time point.
3.	UV spectra of dissolution testing, as recommended by the BP monograph of applied formulation, at all time points of stability study data.	Our UV-spectrophotometer (Insmark 300/2) was not software base due to which prints cannot be taken. Now we have purchased new software of UV-spectrophotometer with print option. Now the firm has submitted UV spectra of dissolution testing of stability batches.
4.	Analytical method verification reports of drug product performed by drug product manufacturer.	Analytical method verification reports of drug product have been provided by performing precision, linearity, accuracy, specificity and system suitability studies.
5.	Evidence of procurement of drug substance with approval from DRAP.	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 wherein the permission to import different APIs Cetirizine Dihydrochloride for the purpose of test/analysis and stability studies is granted. The firm submitted that material was directly received at the plant. Import invoice is attached specifying import of Cetirizine dihydrochloride 0.07 Kg (batch # CTZ/083/20-21).

Decision: Deferred for submission of documents confirming import of API i.e, Goods declaration/ Airway bill/Courier receipt etc.

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Case no. 05: Registration applications of locally manufacturing drugs (human) submitted on Form 5F format (New Section):

On the recommendations of panel of experts, the CLB in its 274th meeting held on 07th April, 2020 has considered and approved the grant of following six (06) additional sections/facilities of your firm M/s Ferozsons Laboratories Ltd, Amangarh, Nowshera, KPK

Ground Floor

1. Tablet Section (General)
2. Ointment / Cream / Gel Section (General)
3. Bottle filling area for Tablets and Capsules
4. Raw Material Store

478.	Name, address of Applicant / Marketing Authorization Holder	M/S Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Name, address of Manufacturing site.	M/S Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Status of the applicant	☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☑ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10871 Dated: 29-04-2022
	Details of fee submitted	PKR 30,000/-: Dated: 07-04-2022
	The proposed proprietary name / brand name	Acylex 5% Cream
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Acyclovir……...50mg
	Pharmaceutical form of applied drug	Cream
	Pharmacotherapeutic Group of (API)	Antiviral for topical use (ATC code: J05AB01)
	Reference to Finished product specifications	B.P. Specifications
	Proposed Pack size	5gm and 10gm tube
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zovirex 5% cream by M/s GlaxoSmithkline Approved by USFDA
	For generic drugs (me-too status)	Zovirex 5% cream by M/s GlaxoSmithkline Pakistan Reg.No 010333
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate valid till 10-08-2023. Ointment/Cream (General) section approved.
	Name and address of API manufacturer.	Name: M/s Zhejiang Zhebei Pharmaceutical Co., Ltd-China Address. No.66 Guo Shantou, Xinshi Town, Deqing County, Zhejiang., China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Official monograph of Acyclovir is present in B.P. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (20120901M, 0120902M, 0120903M)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence.	The Firm has performed pharmaceutical equivalence of their developed formulation Acylex 5% cream (B # AVCream-001) with innovator product Zovirex 5% Cream (B # U389) of M/s GlaxoSmithkline. Quality tests of both products including description, identification, pH, viscosity, Uniformity of container, assay and related substances were performed and compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of drug substance. Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Zhebei Pharmaceutical Co., Ltd-China Address; No.66 Guo Shantou, Xinshi Town, Deqing County, Zhejiang., China
API Lot No.	A200802
Description of Pack (Container closure system)	Aluminum tube

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	AVCream-001	AVCream-002	AVCream-003
Batch Size	600 tubes	600 tubes	600 tubes
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	30-03-2021	30-03-2021	30-03-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of already conducted inspection dated 26-07-2019 for registration application of Hexigard Gel 4% approved in 291st meeting of RB.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of DML of M/s Zhejiang Zhebei Pharmaceutical Co., Ltd.-China issued by Zhejiang province FDA valid till 06-01-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice No.20200824001 specifying import of Acyclovir (1200Kg) dated 28-08-2020 duly attested by Assistant Director DRAP (I&E), Peshawar dated 23-09-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	Clarify why you have tested a USP grade drug substance by applying BP monograph.	The firm has submitted declaration from drug substance manufacturer showing that our Acyclovir (Batch NO.: A200802) meets the requirement of both USP and BP.
2.	You have mentioned test of particle size which is not included in BP monograph.	We have performed particle size test as per our internal specifications to control the API.

Decision: Approved.

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

Case no. 06: Registration applications of locally manufacturing drugs (human) submitted on Form 5 F format

a. New cases

479.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3739 Dated 02-02-2021
	Details of fee submitted	PKR 20,000/-: Dated 09-03-2020 PKR 10,000/-: Dated 22-07-2022
	The proposed proprietary name / brand name	LOPICARD Tablets 5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Amlodipine as besylate…….5mg
	Pharmaceutical form of applied drug	Light yellow colored, octagonal shaped tablet engraved "GETZ" on one side and plain on the other side.
	Pharmacotherapeutic Group of (API)	Calcium Channel Blocker
	Reference to Finished product specifications	USP Specification.
	Proposed Pack size	20's & 30's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	NORVASC Tablet 5mg marketed by M/s Pfizer, USA. USFDA Approved.
	For generic drugs (me-too status)	NORVASC Tablet 5mg marketed by M/s Pfizer, Karachi. (Registration No.: 011825)
	GMP status of the Finished product manufacturer	Last GMP Inspection dated 03-12-2021 concludes that M/s Getz Pharma Pvt. Ltd. is considered to be operating at an acceptable level of compliance of GMP requirements. Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Limited. 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002 .Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance is submitted.

		The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Official monograph of Amlodipine Besylate is available in USP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C±2°C / 75% ± 5%RH for 6 months Batches: (19AD023, 19AD024, 19AD025)
	Module-III (Drug Product):	The firm has submitted details of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted pharmaceutical equivalence and CDP against the innovator product Norvasc Tablet 5mg (Batch # by M/s Pfizer Australia Pty Ltd in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f_2 values are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including System suitability, Specificity, linearity and Precision repeatability.

STABILITY STUDY DATA

Manufacturer of API	M/s Cadila Pharmaceuticals Limited., 294, G.I.D.C. Industrial Estate, Ankleshwar - 393 002, Gujarat, India		
API Lot No.	0000184914 & 0000186073		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton along with leaf insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	010T77	011T77	012T77

Batch Size	400,000 Tablets	400,000 Tablets	400,000 Tablets
Manufacturing Date	12.03.2021	12.03.2021	15.04.2021
Date of Initiation	30.06.2021	30.06.2021	23.08.2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability ✓ Have Data achieving system ✓ Have data integrity ✓ Have Data security ✓ System Security Policy • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are in compliance.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (No. 21102987) for M/s Cadila Pharmaceuticals ltd, India issued by Food and Drug control administration, Gujarat State, India. It is valid till 20-10-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD (I&E) DRAP, Karachi, has been submitted.

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
20ADL008	3202040716	50.0 Kg	31-12-2020
20ADL005	3202140013	150.0 Kg	02-02-2021

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm

<table>
<tr><td>1.</td><td>Analytical method verification studies of drug substance including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer in both module 2 and module 3 shall be submitted.</td><td>The firm has submitted analytical method verification studies from drug product manufacturer by performing system suitability studies, linearity, specificity and precision. We have used 100% API without any placebo in analytical method verification studies, therefore requirement for accuracy is not applicable. Further, we have performed linearity to check area response of the sample as the concentration of sample raised within working range of sample i.e., 50% to 150%.</td></tr>
<tr><td>2.</td><td>The storage conditions under which stability studies of the API conducted were not as per Zone IVA. Clarification is required.</td><td>Stability study data of three batches of drug substance has been submitted as per Zone IVA conditions.</td></tr>
<tr><td>3.</td><td>The copies of complete analysis of at least two batches shall be provided under section 3.2.P.5.4.</td><td>Copies of complete analysis of three batches of Amlodipine 5mg tablet has been submitted.</td></tr>
<tr><td>4.</td><td>The batch numbers and date mentioned in stability summary and conclusions are different from that mentioned in section 3.2.P.5.4. Clarification is required.</td><td>The analytical report of stability batches has been provided.</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP certificate (No. 21102987) for M/s Cadila Pharmaceuticals ltd, India issued by Food and Drug control administration, Gujarat State, India. It is valid till 20-10-2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD (I&E) DRAP, Karachi, has been submitted.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>20ADL008</td><td>3202040716</td><td>50.0 Kg</td><td>31-12-2020</td></tr>
<tr><td>20ADL005</td><td>3202140013</td><td>150.0 Kg</td><td>02-02-2021</td></tr>
</table></td></tr>
<tr><td>7.</td><td>Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets shall be submitted.</td><td>Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>8.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>9.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated).</td></tr>
</table>

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will perform accuracy studies as part of verification studies of analytical method of drug substance before issuance of registration letter.**

<table>
<tr><td rowspan="2">480.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Getz Pharma (Pvt.) Limited
29-30/27, Korangi Industrial Area, Karachi.</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Getz Pharma (Pvt.) Limited</td></tr>
</table>

		29-30/27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3740 Dated 02-02-2021
	Details of fee submitted	PKR 20,000/-: Dated 02-02-2021 PKR 10,000/-: Dated 22-07-2022
	The proposed proprietary name / brand name	LOPICARD Tablets 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Amlodipine as besylate …….10mg
	Pharmaceutical form of applied drug	Light pink colored, oval shaped tablet engraved "GETZ" on one side and "10" on the other side
	Pharmacotherapeutic Group of (API)	Calcium Channel Blocker
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	20's & 30's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	NORVASC Tablet 10mg marketed by M/s Pfizer, USA. (USFDA Approved).
	For generic drugs (me-too status)	NORVASC Tablet 10mg marketed by M/s Pfizer, Karachi (Reg # 011826)
	GMP status of the Finished product manufacturer	Last GMP Inspection dated 03-12-2021 concludes that M/s Getz Pharma Pvt. Ltd. is considered to be operating at an acceptable level of compliance of GMP requirements. Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Limited., 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002, Gujarat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance is submitted. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Module III (Drug Substance)	Official monograph of Amlodipine Besylate is available in USP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C±2°C/ 75% ± 5%RH for 6 months Batches: (19AD023, 19AD024, 19AD025)
	Module-III (Drug Product):	The firm has submitted details of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted pharmaceutical equivalence and CDP against the innovator product Norvasc Tablet 10mg (Batch # by M/s Pfizer Australia Pty Ltd in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f_2 values are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including System suitability, Specificity, linearity and Precision repeatability.

STABILITY STUDY DATA

Manufacturer of API	M/s Cadila Pharmaceuticals Limited., 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002, Gujarat, India.		
API Lot No.	0000184914		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton along with leaf insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	023T78	024T78	025T78
Batch Size	150,000 Tablets	150,000 Tablets	150,000 Tablets
Manufacturing Date	06.03.2021	06.03.2021	27.04.2021
Date of Initiation	23.08.2021	23.08.2021	23.08.2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB

<table>
<tr><td></td><td></td><td>Meeting held on March 15-18, 2022. The inspection report confirms following points:
The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features:
✓ Have Audit trail
✓ Have backup system
✓ Have Data traceability
✓ Have Data achieving system
✓ Have data integrity
✓ Have Data security
✓ System Security Policy
Audit trail on the testing reports is available.
Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
Related manufacturing area, equipment, personnel and utilities are in compliance.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP certificate (No. 21102987) for M/s Cadila Pharmaceuticals ltd, India issued by Food and Drug control administration, Gujarat State, India. It is valid till 20-10-2024.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD (I&E) DRAP, Karachi, has been submitted.<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>20ADL008</td><td>3202040716</td><td>50.0 Kg</td><td>31-12-2020</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated).</td></tr>
<tr><td colspan="3">Remarks of Evaluator:<table><tr><th>Sr. No.</th><th>Observations</th><th>Response by the firm</th></tr><tr><td>1.</td><td>Analytical method verification studies of drug substance including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer in both module 2 and module 3 shall be submitted.</td><td>The firm has submitted analytical method verification studies from drug product manufacturer by performing system suitability studies, linearity, specificity and precision. We have used 100% API without any placebo in analytical method verification studies, therefore requirement for accuracy is not applicable. Further, we have performed linearity to check area response of the sample as the concentration</td></tr></table></td></tr>
</table>

<table>
<tr><td></td><td></td><td>of sample raised within working range of sample i.e., 50% to 150%.</td></tr>
<tr><td>2.</td><td>The storage conditions under which stability studies of the API conducted were not as per Zone IVA. Clarification is required.</td><td>Stability study data of three batches of drug substance has been submitted as per Zone IVA conditions.</td></tr>
<tr><td>3.</td><td>The copies of complete analysis of at least two batches shall be provided under section 3.2.P.5.4.</td><td>Copies of complete analysis of three batches of Amlodipine 10mg tablet has been submitted.</td></tr>
<tr><td>4.</td><td>The batch numbers and date mentioned in stability summary and conclusions are different from that mentioned in section 3.2.P.5.4. Clarification is required.</td><td>The analytical report of stability batches has been provided.</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP certificate (No. 21102987) for M/s Cadila Pharmaceuticals ltd, India issued by Food and Drug control administration, Gujarat State, India. It is valid till 20-10-2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD (I&E) DRAP, Karachi, has been submitted.
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<tr><td>20ADL005</td><td>3202140013</td><td>150.0 Kg</td><td>02-02-2021</td></tr>
</table></td></tr>
<tr><td>7.</td><td>Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets shall be submitted.</td><td>Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>8.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>9.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated).</td></tr>
</table>

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will perform accuracy studies as part of verification studies of analytical method of drug substance before issuance of registration letter.**

481.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25933 Dated 17-09-2021
	Details of fee submitted	PKR 30,000/-: Dated 02-09-2021
	The proposed proprietary name / brand name	Axicart Cream
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Isoconazole Nitrate……10mg Diflucortolone Valerate……..…1mg
	Pharmaceutical form of applied drug	Cream (Topical)
	Pharmacotherapeutic Group of (API)	Isoconazole: Imidazole Antifungals Diflucortolone: Corticosteroids
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	10 gm
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Travocort 0.1 + 1% w/w Cream by M/s Bayer Limited (HPRA Approved)
	For generic drugs (me-too status)	Travocort 0.1 + 1% w/w Cream by M/s Bayer Healthcare (Reg#005830)
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on09-06-2020.
	Name and address of API manufacturer.	**Isoconazole nitrate:** M/s Gufic Biosciences Limited, National highway No. 8, Near Grid, Kabilpore , Navsari – 396 424 Dist: Navsari, Gujarat State, India. **Diflucortolone valerate:** M/s Farmabios S.p.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) , Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity d, g & related substances (impurity a & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies of drug substances	**Isoconazole nitrate:** Stability study conditions: Real time: 30°C±2°C/65% ± 5%RH for 24 months Accelerated:40°C±2°C/75% ± 5%RH for 6 months Batches: 135, 136, 137. **Diflucortolone valerate:** Stability study conditions:

		Real time: 30°C±2°C/65% ± 5%RH for 24 months Accelerated:40°C±2°C/75% ± 5%RH for 6 months Batches: 0030122, 0010222, 002022.
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the reference product Travocort cream (Batch # MP06068) of M/s Bayer Pharma, Germany by performing Identification, pH, Assay and average weight. CDP not performed.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Isoconazole nitrate:** M/s Gufic Biosciences Limited, National highway No. 8, Near Grid, Kabilpore, Navsari – 396 424 Dist: Navsari, Gujarat State, India. **Diflucortolone valerate:** M/s Farmabios S.p.A. Via Pavia, 1 27027 Gropello Cairoli, (PV), Italy.		
API Lot No.	**Isoconazole nitrate:** API/ISN/201006 **Diflucortolone valerate:** 2319VMO		
Description of Pack (Container closure system)	Collapsible aluminum tube with lacquered lining having sealed mouth fitted with HDPE screw cap, 10gm.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	100 tubes	150 tubes	150 tubes
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	06-04-2021	06-04-2021	06-04-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Isoconazole nitrate:** The firm has submitted copy of GMP certificate of M/s Gufic Biosciences Ltd, India issued by Food and Drug Administration, Gujarat State, India valid till 06-08-2022. **Diflucortolone valerate:** The firm has submitted copy of GMP certificate of M/s Farmabios S.p.A, Italy issued by AIFA, Italy valid till 19-09-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Isoconazole nitrate:** The firm has submitted copy of invoice specifying import of 0.25Kgs of isoconazole nitrate cleared by Assistant Director (I & E), Lahore dated 12-02-2021. **Diflucortolone valerate:** The firm has submitted copy of invoice specifying import of 20gm of Diflucortolone valerate cleared by Assistant Director (I & E), Lahore dated 18-02-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers.

Remarks of Evaluator:

Sr. No.	Observations	Response by the applicant
1.	Submit valid copy of GMP certificate of the drug substance manufacturer (Isoconazole nitrate) issued by relevant regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Gufic Biosciences Ltd, India issued by Food and Drug Administration, Gujarat State, India valid till 06-08-2022.
2.	The reference literature shows that inactive ingredients for Travocort 0.1 + 1% w/w Cream include Paraffin, white soft Paraffin, liquid Cetostearyl alcohol, Polysorbate 60, Sorbitan stearate, Disodium edetate dihydrate Water, purified. Justify why you have added span 80 (as non-ionic surfactant), propylene glycol (as humectant) and chlorocresol (as preservative) and not adding sorbitan stearate.	All the inactive ingredients used in the drug product are not novel and routinely used in development of topical drug products. Moreover, compatibility studies were performed and submitted. Spans (Sorbitan stearate & Sorbitan Oleate) are functionally non-ionic surfactants having similar HLB values (4.3 & 4.7 respectively). Due to availability of span 80, it was used instead of span 60. Propylene glycol facilitates in application of drug product by improving moistness and preventing dryness when applied. Chlorocresol was added to help control bio-burden in drug product during shelf life which are inherently added during processing of non-sterile drug product.
3.	Justify why pharmaceutical equivalence study was not performed against innovator product.	Pharmaceutical equivalence study has been performed and submitted against innovator product i.e., Travocort Cream by Bayer.
4.	Performance tests of viscosity and homogeneity were not included in specifications required for evaluation of topical formulation.	Viscosity and homogeneity are not considered performance test for topical dosage form. Moreover, viscosity is formulation dependent parameter and can vary from manufacturer to manufacturer based on availability of difference measuring techniques and instruments and there is no specific limit defined for it in pharmacopoeia. Hence it was not included in the specification. Homogeneity was done through visual inspection as part of physical description of the drug product.
5.	Submit stability study results of initial time point alongwith raw data sheets, COA and summary sheets.	The firm has submitted stability study results of initial time point alongwith raw data sheets, COA.

6.	Submit stability study data of 6-month time point alongwith chromatograms, raw data sheets, COA and summary sheets.	The firm has submitted stability study data of 6-month time point alongwith chromatograms, raw data sheets, COA and summary sheets.
7.	Clarify the submitted chromatograms dated 05-04-2021 pertains to which study.	The chromatograms dated 05-04-2021 are pertaining to initial testing of stability batch trial (T-003 & T-004) respectively.

Decision: Approved with innovator's specifications.

- **Registration Board further decided that registration letter will be issued upon submission of "Preservative effectiveness studies" at the next time point of long-term stability studies. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall be submit fee of 7500/- fee revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

482.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt) Ltd. 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt) Ltd. 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.26412 Dated: 23-09-2021
	Details of fee submitted	PKR 20,000/-: Dated 08-04-2021 PKR 10,000/-: Dated 11-08-2021
	The proposed proprietary name / brand name	ES-LOPROT 10mg SACHET
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Esomeprazole magnesium trihydrate eq. to Esomeprazole ……..….10 mg
	Pharmaceutical form of applied drug	A white to off-white colored enteric coated spherical pellets.
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 10mg gastro resistant granules for oral suspension, sachet Manufactured and Marketed by AstraZeneca UK Limited (MHRA).
	For generic drugs (me-too status)	Esowin Sachet 10mg (Reg. 086891) Manufacturer: M/s. Winthrox Laboratories (Pvt.)
	GMP status of the Finished product manufacturer	The firm is granted GMP Certificate based on inspection conducted on 04-07-2019. Tablet (General & Antibiotic), Capsule (General & Cephalosporin), Dry Powder for Suspension (General Antibiotic &Cephalosporin), Oral Liquid (Syrup) (Non-Antibiotic & Antibiotic), Cream / Ointment /

		Lotion (Non-Antibiotic & Antibiotic & Steroids), Eye & Ear Drops (Non-Antibiotic & Antibiotic & Steroids), Liquid Enema (General), Sachet (General), Small Volume Lyophilized Injectable (Non-Antibiotic, Antibiotic), Gel & Tablet (Hormones) sections approved.
	Name and address of API manufacturer.	M/s Surge Laboratories Pvt. Ltd., 10th Km Faisalabad Road Bikhi District Sheikhupura-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Esomeprazole is USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C±2°C/65% ± 5%RH for 24 months Batches: (EPC-22-WB-001, EPC-22-WB-002, EPC-22-WB-003) Accelerated: 40°C±2°C/75%± 5%RH for 6 months Batches: (EPC-001P, EPC-002P, EPC-003P)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product **Nexium 10 mg** (Batch # RDWT) by AstraZeneca UK Limited by performing quality tests of description, pH, Assay and Microbial limits.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s. Surge Laboratories Pvt. Ltd. 10th KM Faisalabad Road Bikhi, District Sheikhupura.
API Lot No.	EPC-22-WB-119
Description of Pack (Container closure system)	28's Alu Triplex Sachet

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	E001DS01	E001DS02	E001DS03
Batch Size	1.5Kg	1.5Kg	1.5Kg
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	11-12-2019	11-12-2019	11-12-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	Panel Inspection Reports for Tablets Section & Gel Sections was approved in DRB 297th meeting and we got Registration of Solbovir Tablets (Sofosbuvir 400mg) Reg. No.108620, Navosept Gel (Chlorhexidine Gel) Reg. No.107734 while our Capsule Section was approved in 316th Meeting and we got registration of Dexloprot 30mg & 60mg Capsules (Dexlansoprazole) Reg. No. 112582 & 112583).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 170/2019-DRAP (AD-823175-158) issued by Add. Director DRAP, Lahore dated 04-07-2019 valid till 03-07-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice no 19090324-SG dated 26- Sept-2019 – Locally purchased from M/s. Surge, Sheikhupura.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing were not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) submitted.

Remarks of Evaluator:

Sr. No.	Observations	Response by the applicant
1.	Submit copy of latest inspection report or GMP certificate of finished drug product manufacturer.	The firm has submitted copy of GMP certificate based on inspection conducted on 19-09-2020.
2.	Justify the quantity of ready-to-fill pellets used in master formulation keeping in view label claim and potency of pellets	It is stated that each 4.444mg of Esomeprazole magnesium pellets 22.5% contains 1mg of Esomeprazole magnesium. Each 10mg Sachet contains 45.866mg (round off 46.00) of Esomeprazole magnesium pellets (22.5% w/w), calculated as below: 10/22.5 × 100 × 1.032 = 45.866mg
3.	As per WHO recommendations when delayed release products (e.g. Enteric coated) are being compared, the recommended conditions are acid medium (pH 1.2 for 2 hours) and buffer pH 6.8	As per the WHO recommendations to conduct dissolution of delayed release products (e.g. enteric coated) in acid media (pH 1.2 for 2 hours) and buffer pH6.8 medium. We have conducted additional studies in pH 4.5 acetate buffer for

	medium. Justify your CDP studies in three media.	assurance of our product dissolution profile similarity with innovator product in all three media covering the physiological range i.e pH 1.2 Hydrochloric acid, pH 4.5 buffer and pH 6.8 buffer.
4.	Specify the batch size in terms of number of packs prepared instead of providing quantity used to prepare stability batches.	The firm has stated that batch size in terms of packs is 17 packs of 28's. While batch size in terms of bulk weight is 1.50 Kg and in unit quantity 500 sachets.
5.	Reference of previous approval of applications with stability data of the firm (if any).	Panel Inspection Reports for Tablets Section & Gel Sections was approved in DRB 297th meeting and we got Registration of Solbovir Tablets (Sofosbuvir 400mg) Reg. No.108620, Navosept Gel (Chlorhexidine Gel) Reg. No.107734 while our Capsule Section was approved in 316th Meeting and we got registration of Dexloprot 30mg & 60mg Capsules (Dexlansoprazole) Reg. No. 112582 & 112583).
6.	Submit compliance record of HPLC software 21 CFR & audit trail reports on product testing.	Compliance record of HPLC software 21CFR and audit trail reports on product testing.
7.	Submit record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Data of logger record for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted.
8.	Submit purchase invoice specifying purchase of Esomeprazole delayed release pellets for stability batches.	The firm has submitted purchase invoice of Esomeprazole pellets 22.5% (batch No: EPC-22-WB-119) from M/s Surge laboratories (Pvt) Ltd, Lahore.
9.		

Decision: Approved.

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

483.	Name, address of Applicant / Marketing Authorization Holder	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26123 Dated 21-09-2021
	Details of fee submitted	PKR 30,000/- Dated 06-09-2021
	The proposed proprietary name / brand name	Fitbit PFS 20mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml of pre-filled syringe contains: Sodium hyaluronate……20mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anti-Inflammatory, Anti-arthritis

	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	1's, 2's, 5's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	HYALGAN Injection 20mg/2ml by Fidia Farmaceutici S.p.A (AIFA Approved)
	For generic drugs (me-too status)	HYALGAN Injection Manufacture by *Fidia Farmaceutici S.p.A* Imported by: Liakat Pharma, Karachi Marketed by: Matrix Pharma Karachi DRAP Registration no. 031340
	GMP status of the Finished product manufacturer	The firm has submitted copy of GMP certificate based on inspection conducted on 09-11-2020. The firm has provided Biotech (Pre-filled syringe) section.
	Name and address of API manufacturer.	**Name:** M/s Contipro a.s., **Address:** Dolni Dobrouc 401 561 02 Dolni Dobrouc Czech Republic.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of sodium hyaluronate is not present in any Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies of drug substance	Stability study conditions: Long term: 5°C ± 3°C for 36 months Accelerated: 25°C ± 2°C/65% ± 5%RH for 6 months Batches: (071114, 111207, N120815)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the reference product HYALGAN PFS Injection 20mg/2ml (Batch # D01240) of Matrix

		Pharma, Karachi by performing quality tests (Identification, Endotoxin test, Assay. pH). CDP is not required.	
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, Robustness, accuracy, precision (Repeatability), specificity.	
STABILITY STUDY DATA			
Manufacturer of API	**Name:** M/s Contipro a.s. **Address:** Dolni Dobrouc 401 561 02 Dolni Dobrouc Czech Republic.		
API Lot No.	SH-200129-F3		
Description of Pack (Container closure system)	Sterile prefilled syringe with Luer Lock System (Rigid cap), highly resistant borosilicate tubing glass (Type I) (1's, 2's ,5's,10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: Initial, 3, 6 (Months) Real time: Initial, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	500 PFS	500 PFS	500 PFS
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	01-01-2021	01-01-2021	01-01-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to onsite inspection report of their product DASCOT 30mg & 60mg Tablet which was conducted on 26-01-2018, and was presented in 278th meeting of Registration Board. Following was reported in the report: • The HPLC software is 21CFR Compliant. • Audit trail reports were available and physically checked. The firm has data loggers for recording of temperature and humidity.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. sukls72897/2019 issued by Ministerstvo spravedlnosti CR Ministry of Justice of the Czech Republic. Issue & Valid Upto Dt: 15-07-2019 – 15-07-2022.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice specifying import of 0.15 kg of sodium hyaluronate attested by Assistant Director (I & E) dated 08-11-2020.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports on product testing.	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) was submitted.	
Remarks of Evaluator:			

Sr. No.	Observations	Response by the Firm
1.	Submit valid copy of GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin.	Copy of GMP certificate (No. sukls72897/2019) issued by Ministerstvo spravedlnosti CR Ministry of Justice of the Czech Republic has been submitted. Issue & Valid Upto Dt: 15-07-2019 – 15-07-2022.
2.	Confirmation of manufacturing facility / section for the applied formulation.	
3.	Copies of the drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	The firm has submitted copies of the Drug substance specifications and analytical procedures for drug substance by drug product manufacturer.
4.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification protocol and report of the test method for determination of sodium hyaluronate by performing specificity, linearity, accuracy and precision.
5.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of batch manufacturing record of stability batches of drug product.
6.		

Decision: Deferred for following submissions:

- **Confirmation of required manufacturing facility / section from Licensing Division.**
- **Evidence of approval of applied formulation either as pharmaceutical drug product or medical device in reference regulatory authorities/agencies which were adopted by the Registration Board.**
- **Clarification of source of drug substance whether Biological or synthetic.**

484.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24220 Dated: 02-09-2021
	Details of fee submitted	PKR 30,000/-: Dated: 21-06-2021
	The proposed proprietary name / brand name	Protole 20mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Omeprazole enteric coated pellets eq. to omeprazole……20mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	USP Specifications

	Proposed Pack size	14's, 28's, 56's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprzole 20mg Capsule by LANNETT CO INC (USFDA Approved)
	For generic drugs (me-too status)	Opra 20mg Cap by Heal Pharmaceuticals – Peshawar (Reg No: 046135).
	GMP status of the Finished product manufacturer	GMP certificate issued on 04-01-2022 on the basis of inspection conducted on 03-01-2022 General Capsule Section Approved.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Pvt. Ltd Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C/ 65% ± 5%RH for 24 months Accelerated: 40°C±2°C/ 75% ± 5%RH for 6 months Batches: (21E271, 21F243 & 21G104)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the reference product Risek 20mg Capsules by Getz Pharmaceuticals Pvt. Ltd (Batch No 4-163852 & Mfg 08-2019), by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Risek 20mg Capsules by Getz Pharmaceuticals Pvt. Ltd (Batch No 4-163852 & Mfg 08-2019), in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals Pvt. Ltd Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	OMP561, OMP571 & OMP564		
Description of Pack (Container closure system)	02 Alu-Alu blisters, 7 capsules/blister, along with leaflet in a unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 & 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Protole 20mg Capsule			
Batch No.	21A152	20K220	20K218
Batch Size	50,000 Packs	50,000 Packs	50,000 Packs
Manufacturing Date	01-2021	10-2020	10-2020
Date of Initiation	16-01-2021	06-11-2020	25-10-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted Copy of GMP certificate No.F.3/262019-Addl.Dir. (QA&L-I) issued on 31st July 2019, based on evaluation conducted on 10th February 2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Applicable as API Manufacturer is Local
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports on product testing.
6.	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers.

Remarks of Evaluator:

Sr. No.	Observations	Response by the applicant
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that *"Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well*	The firm has submitted method verification data for assay of Omeprazole 8.5% pellets by using HPLC with UV detector. The test method was validated for specificity, linearity, precision, accuracy range, system suitability and robustness.

	as non-compendial drug substance(s) shall be submitted".	
2.	Justify why pharmaceutical equivalence and CDP studies were not performed against innovator product (Losec 20mg Capsule).	Innovator product Losec 20mg Capsule was not commercially available in Pakistan. Therefore, pharmaceutical equivalence and CDP were preformed with locally available brand leader Risek capsule of Getz as per DRAP guidelines.
3.	As per WHO recommendations, when delayed-release products (e.g. enteric coated) are being compared, the recommended conditions are acid medium (pH 1.2) for 2 hours and buffer pH 6.8 medium. Justify your CDP studies in three media.	CDP was performed in 0.1 N HCl for 2 hours followed by buffer pH 6.8. CDP in another buffer pH 4.5 was also performed for separate set of capsules in order to get additional dissolution profile of drug product.
4.	Justify/Clarify the development of commercial scale batches before registration of applied product.	We have submitted the commercial batches data of our export registered product "Prozole 20mg Capsule" Registration # 002575-EX, registered in 2010 for our local registration of Protole 20mg capsule.
5.	Submit purchase invoice specifying purchase of omeprazole delayed release pellets for stability batches.	The firm has submitted invoices of omeprazole delayed release pellets 8.5% from M/s Vision Pharmaceuticals for following batches: OMP561 OMP564 OMP571

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer shall perform pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product i.e. Losec 20mg Capsule before issuance of Registration Letter.**

485.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Limited, Address: B-18, S.I.T.E., Karachi -75700, Karachi.
	Name, address of Manufacturing site.	M/s Atco Laboratories Limited, Address: B-18, S.I.T.E., Karachi -75700, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25928 Dated: 17-09-2021 Dated 17- 09-2021 (with three month stability) Dated 11-11-2021 (with six months stability)
	Details of fee submitted	PKR 30,000/-: Dated 01-09-2021
	The proposed proprietary name / brand name	TOFACITINIB TABLET 5 MG
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tofacitinib as Citrate……..……..5mg
	Pharmaceutical form of applied drug	Film coated Tablet

	Pharmacotherapeutic Group of (API)	Selective immunosuppressants
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 60's, 180's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XELJANZ 5mg Tablet of M/s PF PRISM CV (USFDA approved).
	For generic drugs (me-too status)	**Importer Name:** M/s Pfizer Pakistan Limited, 12 Dockyard Road, West Wharf, Karachi. **Name and address of manufacturer:** Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg Mooswaldallee 1 79090 Freiburg, Germany Final Packaging & Release: Pfizer Pharmaceuticlas LLC Road 689, Km 1.9 Vega Baja, Peurto rico 00693, USA Brand Name: Xelijanz 5mg tablet Registration No: Approved in DRB 276th, Dated: 22-25 November, 2017
	GMP status of the Finished product manufacturer	The firm has submitted copy of inspection report conducted on 05-04-2022 wherein the panel recommended the grant of renewal of Drug manufacturing license of the firm as well as regularization of sections as per layout plan.
	Name and address of API manufacturer.	M/s Kaifeng Pharmaceutical (Group) Company Limited., **Manufacturing Site**: No.1, Yunan Street, Kaifeng, Henan Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies	Stability study conditions: Real time:30°C±2°C/65% ± 5%RH for 6 months Accelerated:40°C±2°C/75%±5%RH for 6 months Batches: (15012401, 15020201, 15020301)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Xeljanz 5mg Tablet (Batch # DE4156)** by **Pfizer Laboratories Ltd** by performing quality tests (Identification, Assay, Dissolution and related substances). CDP has been performed against the same brand that is **Xeljanz 5mg Tablet** by Pfizer Laboratories Ltd in Acid media (pH 1.0-1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f_1 and f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kaifeng Pharmaceutical (Group) Company Limited., Manufacturing Site: No.1, Yunan Street, Kaifeng, Henan Province, China.		
API Lot No.	HF201230		
Description of Pack (Container closure system)	1 × 10's tablets packed in Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MA109C	MA110C	MA111C
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	26-03-2021	26-03-2021	26-03-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of previous approval of application "Rofl 500mg tablet" Approved in DRB 277 held on 27-29 December 2017.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Kaifeng pharmaceutical (Group) issued by CFDA valid till 25-06-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice specifying import of 0.8 Kgs of Tofacitinib citrate (batch # HF201230) attested by Assistant Director (I & E), Karachi dated 28-09-2024.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	Last GMP inspection report conducted within 3 years is required to be submitted.	The firm has submitted copy of inspection report conducted on 05-04-2022 wherein the panel recommended the grant of renewal of Drug manufacturing license of the firm as well as regularization of sections as per layout plan.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Analytical method verification studies including specificity, accuracy, and repeatability performed by drug product manufacturer for drug substance Tofacitinib citrate has been submitted.
3.	Submit stability study data of 6-month time point alongwith chromatograms, raw data sheets, COA and summary sheets.	The firm has submitted stability study data of 06-month time point alongwith chromatograms, raw data sheets, COA and summary sheets.

Decision: Approved.

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

486.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Limited., Address: B-18, S.I.T.E., Karachi -75700, Karachi.
	Name, address of Manufacturing site.	M/s Atco Laboratories Limited, Address: B-18, S.I.T.E., Karachi -75700, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25006 Dated: 09-09-2021 Dated 09-09-2021 (with three month stability) Dated 11-11-2021 (with six months stability)
	Details of fee submitted	PKR 30,000/-: Dated 12-08-2021
	The proposed proprietary name / brand name	EXEMESTANE TABLET 25 MG
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Exemestane……25mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Aromatase inhibitors; WHO ATC code: L02BG06
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	7's, 10's, 14's, 15's, 20's, 28's, 30's, 60's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exemestane 25 mg Film-coated Tablets of Accord Healthcare Limited United Kingdom (MHRA approved)

	For generic drugs (me-too status)	Aromasin 25mg tablet of M/s Pfizer Laboratories.
	GMP status of the Finished product manufacturer	The firm has submitted copy of inspection report conducted on 05-04-2022 wherein the panel recommended the grant of renewal of Drug manufacturing license of the firm as well as regularization of sections as per layout plan.
	Name and address of API manufacturer.	M/s Shandong Anhong Pharmaceutical Co., Ltd. No.29 Huayuan Street Linyi County, Dezhou, Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies	Stability study conditions: Real time: 30°C±2°C/ 65% ± 5%RH for 24 months Accelerated: 40°C±2°C / 75% ± 5%RH for 6 months Batches: (8024P71A, 8025P71A, 8026P71A).
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the reference product Aromasin 25mg tablet (batch # AN4319) of Pfizer Laboratories Ltd by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Aromasin 25mg tablet by Pfizer Laboratories Ltd in Acid media (pH 1.0-1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f_1 and f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Shandong Anhong Pharmaceutical Co., Ltd. No.29 Huayuan Street Linyi County, Dezhou, Shandong, China	

API Lot No.	0020P71A		
Description of Pack (Container closure system)	1 × 10's tablets packed in Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (months) Real Time: 0,3,6,9,12,18,24 (months)		
Batch No.	MA092C	MA093C	MA094C
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	08-03-2021	08-03-2021	08-03-2021
Date of Initiation	19-03-2021	19-03-2021	19-03-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of previous approval of application "Rofl 500mg tablet" Approved in DRB 277 held on 27-29 December 2017.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Qilu Antibiotics (Linyi) Pharmaceutical Co. Ltd, China issued by CFDA valid till 25-06-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice specifying import of 0.75 Kg of Exemestane (batch # 0020P71A) attested by Assistant Director (I & E), Karachi dated 22-01-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	Last GMP inspection report conducted within 3 years is required to be submitted.	The firm has submitted copy of inspection report conducted on 05-04-2022 wherein the panel recommended the grant of renewal of Drug manufacturing license of the firm as well as regularization of sections as per layout plan.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Analytical method verification studies including specificity, accuracy, and repeatability performed by drug product manufacturer for the assay method of drug substance Exemestane has been submitted.
3.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug	Copies of Batch manufacturing record of all the batch drug product have been provided.

	product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
4.	Justify performance of comparative dissolution study in three media in the presence of sodium lauryl sulphate	As per NDA 20-753 Assessment report (Clinical pharmacology and Biopharmaceutics review) of Aromasin 25mg Tablet, Exemestane is poorly soluble in all aqueous media simulating gastrointestinal fluids such that sink conditions cannot be reached even at ___ minutes (Hidden in innovator's assessment report) from the 25mg Tablet in water, simulated gastric fluid pH 1.2 and phosphate buffer 6.8. The sponsor then investigated the possibility of enhancing the solubility of Exemestane in aqueous media by addition of sodium lauryl sulphate. *However, the referred literature is for selection of dissolution method and specification.*
5.	The submitted copy of GMP certificate of API manufacturer is from Qilu Antibiotics (Linyi) Pharmaceutical Co. Ltd, China while COA is from M/s Shandong Anhong Pharmaceutical Co., Ltd. China.	Shandong Qilu Pharmaceutical Group has changed their name from Qilu Antibiotics Pharmaceutical Co., Ltd to Shandong Anhong pharmaceutical Co., Ltd effective from February 1, 2020. According to previous CFDA regulation, the original GMP certificates are still in valid and there is no need to be revised. Change approval / change notification with original GMP certificate have been attached.
6.	Submit stability study data of 6-smonth time point alongwith chromatograms, raw data sheets, COA and summary sheets.	The firm has submitted stability study data of 06-month time point alongwith chromatograms, raw data sheets, COA and summary sheets.

Decision: Approved.

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

487.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25008 Dated 08-09-2021
	Details of fee submitted	PKR 20,000/-: Dated: 07-07-2021 PKR 10,000/-: Dated: 30-06-2021
	The proposed proprietary name / brand name	Lodopin-VHCT 10mg+160mg+25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine as Besylate……...10mg Valsartan Potassium…….160mg Hydrochlorothiazide……..25mg
	Pharmaceutical form of applied drug	Brown Color, Oblong Biconvex film coated tablets on one side engraved with M-D and plain from another side.

	Pharmacotherapeutic Group of (API)	Calcium channel blocker Angiotensin II receptor blocker (ARB) Thiazide diuretic (Anti-hypertensive)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT 10+160+25mg tablet by M/s Novartis Pharmaceuticals Corporation, USFDA Approved.
	For generic drugs (me-too status)	Exforge HCT 10+160+25mg tablet by M/s Novartis (Pakistan) Limited, DRAP Approved.
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021. Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Name and address of API manufacturer.	**Amlodipine:** M/s Prudence Pharma chem, Plot No. 7407, Behind lakya lab, GIDC Ind. Estate, Ankleshwar -393 002 Dist. Bharuch, Gujarat, INDIA. **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co., Ltd. No. 6, North Airport Road, Sanazao Town, Jinwan District, Zhuhai City, Guangdong province, 519041, P.R. of China. **Hydrochlorothiazide:** M/s Changzhou Pharma, No.518 Laodong East Road, Changzhou, Jiangsu Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75%±5%RH for 6 months Batches: NPD-T-659-P, NPD-T-632-L, NPD-T-658-P
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established between test formulation (Batch # BMJ 27) against the reference product Exforge HCT 5/160/25 mg tablet (Batch # NPD-T-1348-T) by M/s Novartis Farmaceutica S.A., Barcelona Spain by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against Exforge HCT 10+160+25mg tablet by M/s Novartis Farmaceutica S.A., Barcelona Spain in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Amlodipine:** M/s Prudence Pharmachem, Gujarat (India). **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co. Ltd. China. **Hydrochlorothiazide:** M/s Changzhou Pharmaceutical, China.		
API Lot No.	**Amlodipine:** AMB/081/07/19 & AMB/082/07/19 **Valsartan:** 67819100605 **Hydrochlorothiazide:** EH180407		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Lodopin-VHCT 10mg+160mg+25mg Tablet			
Batch No.	NPD-T-658-P	NPD-T-632-L	NPD-T-659-P
Batch Size	10,000 Tablets	10,000 Tablets	10,000 Tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	04-2020	05-2020	06-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted registration letter of Glucovance Tablet 1000mg/5mg.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**M/s Prudence Pharmachem:** The firm has submitted copy of retention of license to manufacture for sale of drugs. License in Form-25, No No G/25/1656 has been retained from 08-04-2020 to 07-04-2025. **M/s Zhuhai Rundu:** Copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration has been submitted. It is valid till 10-04-2024. **M/s Changzhou Pharmaceutical:** GMP Certificate No JS20180848 issued by CFDA valid till 09-07-2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine besylate:** The firm has submitted copy of invoice specifying import of Amlodipine besylate (Batch#AMB/082/04/19, 300Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 09-07-2019. **Valsartan:** The firm has submitted copy of invoice specifying import of Valsartan (Batch#67819100605, 150Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 26-02-2020. **Hydrochlorothiazide:** The firm has submitted copy of invoice specifying import of Hydrochlorothiazide (EH180407, 15Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 02-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted audit trail record for dissolution and assay testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No	Observations communicated	Response by the firm
1.	The label claim of applied formulation does not define the equivalency of salt form of amlodipine besylate. Corrrection / clarification is required.	The firm has corrected the label claim of amlodipine besylate in applied formulation.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted method verification study of testing method of Lodopin VHCT Tablet by performing parameters like precision, linearity and accuracy.
3.	The reference literature shows that inactive ingredients for all strengths of the tablets include microcrystalline cellulose; crospovidone; colloidal anhydrous silica; magnesium stearate; hypromellose, macrogol 4000 and talc. Justify your formulation development in line with innovator product without addition of Hypromellose, macrogol 4000 and talc.	The firm replied that some of the excipients are not being used in the formulation like, Hypromellose, Macrogol 4000 & Talc. The mentioned excipients are used for coating purpose only. Therefore, we have used the ready-made film coating materials to make the film process simpler, easier to automate and enhances the elegance and glossy appearance of the coated tablets.
4.	Clarify the use of nomenclature process performance qualification protocol instead of adopting process validation protocol.	The firm has submitted process validation protocol of Lodopin VHCT Tablets.
5.	Justify why accuracy parameter was not studied in analytical method validation study for assay testing of drug product. Moreover, results of analytical method validation studies are required to be tabulated properly for Module 3.	The firm has submitted analytical method validation studies of testing method of Lodopin VHCT Tablet by performing linearity, accuracy precision.
6.	In this section, only summary of batch analysis release results of two batches has been submitted. Provide complete analysis details of two batches for which stability study has been conducted.	Complete analysis details of three batches has been submitted.

7.	The results of batch analysis and stability data reflect that test of uniformity of dosage unit has not been performed.	The firm has submitted performance of content uniformity test by individual assay of 10 tablets of Lodopin VHCT tablets for each amlodipine as besylate, valsartan and hydrochlorothiazide by HPLC.
8.	Justify the manufacturing of stability batches on 05-2019 since amlodipine besylate and Valsartan are cleared on 07-2019 and 02-2020, respectively as per the documents for import of drug substances submitted.	Valsartan: The firm has submitted that M/s. Martin Dow Marker Limited & M/s. Martin Dow limited perform function under the umbrella of Martin Dow group (same management). *So, when we were developing formulation of Lodopin VHCT in May 2019 at Martin Dow Marker limited, 7-Jail road Quetta, we procured Valsartan from M/s Martin Dow Limited, Karachi only for development purpose (ADC invoice) attached for reference.* Here, we undertake that in future for commercialization of above product we will procure Valsartan from same source. The firm has submitted copy of invoice for the purchase of Valsartan (90Kg) attested by AD (I&E), Karachi dated 19-07-2016. Amlodipine: *We, M/s Martin Dow Marker limited apologize for mistakenly putting the wrong invoice in the dossier, the correct invoice is attached to this file.* The firm has submitted copy of invoice for the purchase of Amlodipine besylate (100Kg) attested by AD (I&E), Quetta dated 26-03-2019.
9.	Provide copy of Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMR of the stability batches for the drug product. *However, manufacturing date on BMR was 04-2020 while initially submitted stability data showed manufacturing date of 05-2019.* The firm again submitted that there is some typo error in BMR, so we will provide revised BMR accordingly.
10.	Submit updated copy of GMP certificate of drug substance manufacturer of Valsartan.	The firm has submitted copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration. It is valid till 10-04-2024.
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 7500/- fee for revision of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

488.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24849 Dated 08-09-2021
	Details of fee submitted	PKR 20,000/-: Dated: 07-07-2021 PKR 10,000/-: Dated: 30-06-2021
	The proposed proprietary name / brand name	Lodopin-VHCT 10mg+160mg+12.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine as Besylate...…...10mg Valsartan …….……..160mg Hydrochlorothiazide……..12.5mg
	Pharmaceutical form of applied drug	White to off white, Oblong Biconvex film coated tablets on one side engraved with M-D and plan from another side
	Pharmacotherapeutic Group of (API)	Calcium channel blocker Angiotensin II receptor blocker (ARB) Thiazide diuretic (Anti-hypertensive)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT 10+160+12.5mg tablet by M/s Novartis Pharmaceuticals Corporation, USFDA Approved.
	For generic drugs (me-too status)	Exforge HCT 10+160+12.5mg tablet by M/s Novartis (Pakistan) Limited, DRAP Approved.
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021. Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Name and address of API manufacturer.	**Amlodipine:** M/s Prudence Pharma chem, Plot No. 7407, Behind lakya lab, GIDC Ind. Estate, Ankleshwar -393 002 Dist. Bharuch, Gujarat, INDIA. **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co., Ltd. No. 6, North Airport Road, Sanazao Town, Jinwan District, Zhuhai City, Guangdong province, 519041, P.R. of China. **Hydrochlorothiazide:** M/s Changzhou Pharma, No.518 Laodong East Road, Changzhou, Jiangsu Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: NPD-T-655-P, NPD-T-631-L, NPD-T-657-P
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Exforge HCT 5/160/25 mg tablet** by **M/s Novartis Farmaceutica S.A., Barcelona Spain** by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is **Exforge HCT 10+160+12.5mg tablet by M/s Novartis Farmaceutica S.A., Barcelona Spain** in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f_1 and f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Amlodipine:** M/s Prudence Pharmachem, Gujarat (India) **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co. Ltd. China **Hydrochlorothiazide:** M/s Changzhou Pharmaceutical, China		
API Lot No.	**Amlodipine:** AMB/081/07/19 & AMB/082/07/19 **Valsartan:** 67819100605 **Hydrochlorothiazide:** EH180407		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Lodopin-VHCT 10mg+160mg+12.5mg Tablet			
Batch No.	NPD-T-657-P	NPD-T-631-L	NPD-T-656-P
Batch Size	10,000 Tablets	10,000 Tablets	10,000 Tablets
Manufacturing Date	04-2020	04-2020	04-2020

Date of Initiation	04-2020	05-2020	04-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted registration letter of Glucovance Tablet 1000mg/5mg.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**M/s Prudence Pharmachem:** The firm has submitted copy of retention of license to manufacture for sale of drugs. License in Form-25, No No G/25/1656 has been retained from 08-04-2020 to 07-04-2025. **M/s Zhuhai Rundu:** Copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration has been submitted. It is valid till 10-04-2024. **M/s Changzhou Pharmaceutical:** GMP Certificate No JS20180848 issued by CFDA valid till 09-07-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine besylate:** The firm has submitted copy of invoice specifying import of Amlodipine besylate (Batch#AMB/082/04/19, 300Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 09-07-2019. **Valsartan:** The firm has submitted copy of invoice specifying import of Valsartan (Batch#67819100605, 150Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 26-02-2020. **Hydrochlorothiazide:** The firm has submitted copy of invoice specifying import of Hydrochlorothiazide (EH180407, 15Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 02-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted audit trail record for dissolution and assay testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No	Observations communicated	Response by the firm
1.	The label claim of applied formulation does not define the equivalency of salt form of amlodipine besylate. Corrrection / clarification is required.	The firm has corrected the label claim of amlodipine besylate in applied formulation.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted method verification study of testing method of Lodopin VHCT Tablet by performing parameters like precision, linearity and accuracy.
3.	The reference literature shows that inactive ingredients for all strengths of the tablets include microcrystalline cellulose; crospovidone; colloidal anhydrous silica; magnesium stearate; hypromellose, macrogol 4000 and talc. Justify your formulation development in line with innovator product	The firm replied that some of the excipients are not being used in the formulation like, Hypromellose, Macrogol 4000 & Talc. The mentioned excipients are used for coating purpose only. Therefore, we have used the ready-made film coating materials to make the film process simpler, easier to automate

	without addition of Hypromellose, macrogol 4000 and talc.	and enhances the elegance and glossy appearance of the coated tablets.
4.	Clarify the use of nomenclature process performance qualification protocol instead of adopting process validation protocol.	The firm has submitted process validation protocol of Lodopin VHCT Tablets.
5.	Justify why accuracy parameter was not studied in analytical method validation study for assay testing of drug product. Moreover, results of analytical method validation studies are required to be tabulated properly for Module 3.	The firm has submitted analytical method validation studies of testing method of Lodopin VHCT Tablet by performing linearity, accuracy precision.
6.	In this section, only summary of batch analysis release results of two batches has been submitted. Provide complete analysis details of two batches for which stability study has been conducted.	Complete analysis details of three batches has been submitted.
7.	The results of batch analysis and stability data reflect that test of uniformity of dosage unit has not been performed.	The firm has submitted performance of content uniformity test by individual assay of 10 tablets of Lodopin VHCT tablets for each amlodipine as besylate, valsartan and hydrochlorothiazide by HPLC.
8.	Justify the manufacturing of stability batches on 05-2019 since amlodipine besylate and Valsartan are cleared on 07-2019 and 02-2020, respectively as per the documents for import of drug substances submitted.	<u>Valsartan:</u> The firm has submitted that M/s. Martin Dow Marker Limited & M/s. Martin Dow limited perform function under the umbrella of Martin Dow group (same management). *So, when we were developing formulation of Lodopin VHCT in May 2019 at Martin Dow Marker limited, 7-Jail road Quetta, we procured Valsartan from M/s Martin Dow Limited, Karachi only for development purpose (ADC invoice) attached for reference.* Here, we undertake that in future for commercialization of above product we will procure Valsartan from same source. The firm has submitted copy of invoice for the purchase of Valsartan (90Kg) attested by AD (I&E), Karachi dated 19-07-2016. <u>Amlodipine:</u> *We, M/s Martin Dow Marker limited apologize for mistakenly putting the wrong invoice in the dossier, the correct invoice is attached to this file.* The firm has submitted copy of invoice for the purchase of Amlodipine besylate (100Kg) attested by AD (I&E), Quetta dated 26-03-2019.
9.	Provide copy of Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMR of the stability batches for the drug product. *However, manufacturing date on BMR was 04-2020 while initially submitted stability data showed manufacturing date of 05-2019.* The firm again submitted that there is some typo error in BMR, so we will provide revised BMR accordingly.
10.	Submit updated copy of GMP certificate of drug substance manufacturer of Valsartan.	The firm has submitted copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration. It is valid till 10-04-2024.
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration Board further decided that registration letter will be issued after submission of 7500/- fee for revision of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
489.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta.
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24850 Dated 08-09-2021
	Details of fee submitted	PKR 20,000/-: Dated: 07-07-2021 PKR 10,000/-: Dated: 30-06-2021
	The proposed proprietary name / brand name	Lodopin-VHCT 10mg+320mg+25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine as Besylate…….....10mg Valsartan……....…….....320mg Hydrochlorothiazide….…….25mg
	Pharmaceutical form of applied drug	Dark Brown Color, Oblong Biconvex film coated tablets on one side engraved with M-D and plain from another side
	Pharmacotherapeutic Group of (API)	Calcium channel blocker Angiotensin II receptor blocker (ARB) Thiazide diuretic (Anti-hypertensive)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT 10+320+25mg tablet by M/s Novartis Pharmaceuticals Corporation, USFDA Approved.
	For generic drugs (me-too status)	Exforge HCT 10+320+25mg tablet by M/s Novartis (Pakistan) Limited, DRAP Approved.
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Name and address of API manufacturer.	**Amlodipine:** M/s Prudence Pharma chem, Plot No. 7407, Behind lakya lab, GIDC Ind. Estate, Ankleshwar -393 002 Dist. Bharuch, Gujarat, INDIA. **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co., Ltd. No. 6, North Airport Road, Sanazao Town, Jinwan

		District, Zhuhai City, Guangdong province, 519041, P.R. of China. **Hydrochlorothiazide:** M/s Changzhou Pharma, No.518 Laodong East Road, Changzhou, Jiangsu Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Real Time**: NPD-T-660-P, NPD-T-633-L, NPD-T-661-P, **Accelerated Time:** NPD-T-660-P, NPD-T-633-L, NPD-T-661-P,
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Exforge HCT 5/320/25 mg tablet by M/s Novartis Farmaceutica S.A., Barcelona Spain** by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is **Exforge HCT 10+320+25mg tablet by M/s Novartis Farmaceutica S.A., Barcelona Spain** in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	**Amlodipine:** M/s Prudence Pharmachem, Gujarat, India. **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co. Ltd. China. **Hydrochlorothiazide:** M/s Changzhou Pharmaceutical, China.	

API Lot No.	**Amlodipine:** AMB/081/07/19 & AMB/082/07/19 **Valsartan:** 67819100605 **Hydrochlorothiazide:** EH180407		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Lodopin-VHCT 10mg+320mg+25mg Tablet			
Batch No.	NPD-T-661-P	NPD-T-633-L	NPD-T-660-P
Batch Size	10000 Tablets	10000 Tablets	10000 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	01-2022	01-2022	01-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted registration letter of Glucovance Tablet 1000mg/5mg.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**M/s Prudence Pharmachem:** The firm has submitted copy of retention of license to manufacture for sale of drugs. License in Form-25, No No G/25/1656 has been retained from 08-04-2020 to 07-04-2025. **M/s Zhuhai Rundu:** Copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration has been submitted. It is valid till 10-04-2024. **M/s Changzhou Pharmaceutical:** GMP Certificate No JS20180848 issued by CFDA valid till 09-07-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine besylate:** The firm has submitted copy of invoice specifying import of Amlodipine besylate (Batch#AMB/082/04/19, 300Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 09-07-2019. **Valsartan:** The firm has submitted copy of invoice specifying import of Valsartan (Batch#67819100605, 150Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 26-02-2020. **Hydrochlorothiazide:** The firm has submitted copy of invoice specifying import of Hydrochlorothiazide (EH180407, 15Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 02-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted audit trail record for dissolution and assay testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		

Sr. No	Observations communicated	Response by the firm
1.	The label claim of applied formulation does not define the equivalency of salt form of amlodipine besylate. Corrrection / clarification is required.	The firm has corrected the label claim of amlodipine besylate in applied formulation.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted method verification study of testing method of Lodopin VHCT Tablet by performing parameters like precision, linearity and accuracy.
3.	The reference literature shows that inactive ingredients for all strengths of the tablets include microcrystalline cellulose; crospovidone; colloidal anhydrous silica; magnesium stearate; hypromellose, macrogol 4000 and talc. Justify your formulation development in line with innovator product without addition of Hypromellose, macrogol 4000 and talc.	The firm replied that some of the excipients are not being used in the formulation like, Hypromellose, Macrogol 4000 & Talc. The mentioned excipients are used for coating purpose only. Therefore, we have used the ready-made film coating materials to make the film process simpler, easier to automate and enhances the elegance and glossy appearance of the coated tablets.
4.	Clarify the use of nomenclature process performance qualification protocol instead of adopting process validation protocol.	The firm has submitted process validation protocol of Lodopin VHCT Tablets.
5.	Justify why accuracy parameter was not studied in analytical method validation study for assay testing of drug product. Moreover, results of analytical method validation studies are required to be tabulated properly for Module 3.	The firm has submitted analytical method validation studies of testing method of Lodopin VHCT Tablet by performing linearity, accuracy precision.
6.	In this section, only summary of batch analysis release results of two batches has been submitted. Provide complete analysis details of two batches for which stability study has been conducted.	Complete analysis details of three batches has been submitted.
7.	The results of batch analysis and stability data reflect that test of uniformity of dosage unit has not been performed.	The firm has submitted performance of content uniformity test by individual assay of 10 tablets of Lodopin VHCT tablets for each amlodipine as besylate, valsartan and hydrochlorothiazide by HPLC.
8.	Justify the manufacturing of stability batches on 05-2019 since amlodipine besylate and Valsartan are cleared on 07-2019 and 02-2020, respectively as per the documents for import of drug substances submitted.	<u>Valsartan:</u> The firm has submitted that M/s. Martin Dow Marker Limited & M/s. Martin Dow limited perform function under the umbrella of Martin Dow group (same management). *So, when we were developing formulation of Lodopin VHCT in May 2019 at Martin Dow Marker limited, 7-Jail road Quetta, we procured Valsartan from M/s Martin Dow Limited, Karachi only for development purpose (ADC invoice) attached for reference.* Here, we undertake that in future for commercialization of above product we will procure Valsartan from same source. The firm has submitted copy of invoice for the purchase of Valsartan (90Kg) attested by AD (I&E), Karachi dated 19-07-2016. <u>Amlodipine:</u> *We, M/s Martin Dow Marker limited apologize for mistakenly putting the wrong invoice in the dossier, the correct invoice is attached to this file.*

		The firm has submitted copy of invoice for the purchase of Amlodipine besylate (100Kg) attested by AD (I&E), Quetta dated 26-03-2019.
9.	Provide copy of Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMR of the stability batches for the drug product. *However, manufacturing date on BMR was 04-2020 while initially submitted stability data showed manufacturing date of 05-2019.* The firm again submitted that there is some typo error in BMR, so we will provide revised BMR accordingly.
10.	Submit updated copy of GMP certificate of drug substance manufacturer of Valsartan.	The firm has submitted copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration. It is valid till 10-04-2024.
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 7500/- fee for revision of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

490.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta.
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25007 Dated 08-09-2021
	Details of fee submitted	PKR 20,000/-: Dated: 07-07-2021 PKR 10,000/-: Dated: 30-06-2021
	The proposed proprietary name / brand name	Lodopin-VHCT 5mg+160mg+12.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine as besylate……...5mg Valsartan……....160mg Hydrochlorothiazide……....12.5mg
	Pharmaceutical form of applied drug	White to Off white, Oblong Biconvex film coated tablets on one side engraved with M-D and plan from another side
	Pharmacotherapeutic Group of (API)	Calcium channel blocker Angiotensin II receptor blocker (ARB) Thiazide diuretic (Anti-hypertensive)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per DPC

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT 5/160/12.5 mg tablet by M/s Novartis Pharmaceuticals Corporation, USFDA Approved.
	For generic drugs (me-too status)	Exforge HCT 5/160/12.5 mg tablet by M/s Novartis (Pakistan) Limited, DRAP Approved.
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021. Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Name and address of API manufacturer.	**Amlodipine:** M/s Prudence Pharma chem, Plot No. 7407, Behind lakya lab, GIDC Ind. Estate, Ankleshwar -393 002 Dist. Bharuch, Gujarat, INDIA. **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co., Ltd. No. 6, North Airport Road, Sanazao Town, Jinwan District, Zhuhai City, Guangdong province, 519041, P.R. of China. **Hydrochlorothiazide:** M/s Changzhou Pharma, No.518 Laodong East Road, Changzhou, Jiangsu Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies of Drug Substance	Stability study conditions: Amlodipine besylate: Valsartan: Hydrochlorothiazide:
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the reference product, Exforge HCT 5/160/12.5 mg tablet by M/s Novartis Farmaceutica S.A., Barcelona

		Spain by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is Exforge HCT 5/160/12.5 mg tablet by M/s Novartis Farmaceutica S.A., Barcelona Spain in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Amlodipine:** M/s Prudence Pharmachem, Gujarat (India) **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co. Ltd. China **Hydrochlorothiazide:** M/s Changzhou Pharmaceutical, China		
API Lot No.	**Amlodipine:** AMB/081/07/19 & AMB/082/07/19 **Valsartan:** 67819100605 **Hydrochlorothiazide:** EH180407		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Lodopin-VHCT 5mg+160mg+12.5mg Tablet			
Batch No.	NPD-T-653-P	NPD-T-629-L	NPD-T-652-P
Batch Size	10,000 Tablets	10,000 Tablets	10,000 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	01-2020	01-2020	01-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted registration letter of Glucovance Tablet 1000mg/5mg.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**M/s Prudence Pharmachem:** The firm has submitted copy of retention of license to manufacture for sale of drugs. License in Form-25, No No G/25/1656 has been retained from 08-04-2020 to 07-04-2025. **M/s Zhuhai Rundu:** Copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration has been submitted. It is valid till 10-04-2024. **M/s Changzhou Pharmaceutical:** GMP Certificate No JS20180848 issued by CFDA valid till 09-07-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine besylate:** The firm has submitted copy of invoice specifying import of Amlodipine besylate (Batch#AMB/082/04/19, 300Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 09-07-2019. **Valsartan:** The firm has submitted copy of invoice specifying import of Valsartan (Batch#67819100605, 150Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 26-02-2020. **Hydrochlorothiazide:** The firm has submitted copy of invoice specifying import of Hydrochlorothiazide

		(EH180407, 15Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 02-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted audit trail record for dissolution and assay testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No	Observations communicated	Response by the firm
1.	The label claim of applied formulation does not define the equivalency of salt form of amlodipine besylate. Corrrection / clarification is required.	The firm has corrected the label claim of amlodipine besylate in applied formulation.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted method verification study of testing method of Lodopin VHCT Tablet by performing parameters like precision, linearity and accuracy.
3.	The reference literature shows that inactive ingredients for all strengths of the tablets include microcrystalline cellulose; crospovidone; colloidal anhydrous silica; magnesium stearate; hypromellose, macrogol 4000 and talc. Justify your formulation development in line with innovator product without addition of Hypromellose, macrogol 4000 and talc.	The firm replied that some of the excipients are not being used in the formulation like, Hypromellose, Macrogol 4000 & Talc. The mentioned excipients are used for coating purpose only. Therefore, we have used the ready-made film coating materials to make the film process simpler, easier to automate and enhances the elegance and glossy appearance of the coated tablets.
4.	Clarify the use of nomenclature process performance qualification protocol instead of adopting process validation protocol.	The firm has submitted process validation protocol of Lodopin VHCT Tablets.
5.	Justify why accuracy parameter was not studied in analytical method validation study for assay testing of drug product. Moreover, results of analytical method validation studies are required to be tabulated properly for Module 3.	The firm has submitted analytical method validation studies of testing method of Lodopin VHCT Tablet by performing linearity, accuracy precision.
6.	In this section, only summary of batch analysis release results of two batches has been submitted. Provide complete analysis details of two batches for which stability study has been conducted.	Complete analysis details of three batches has been submitted.
7.	The results of batch analysis and stability data reflect that test of uniformity of dosage unit has not been performed.	The firm has submitted performance of content uniformity test by individual assay of 10 tablets of Lodopin VHCT tablets for each amlodipine as besylate, valsartan and hydrochlorothiazide by HPLC.
8.	Justify the manufacturing of stability batches on 05-2019 since amlodipine besylate and Valsartan are cleared on 07-2019 and 02-2020,	Valsartan: The firm has submitted that M/s. Martin Dow Marker Limited & M/s. Martin Dow limited perform function under the umbrella of Martin Dow group

	respectively as per the documents for import of drug substances submitted.	(same management). *So, when we were developing formulation of Lodopin VHCT in May 2019 at Martin Dow Marker limited, 7-Jail road Quetta, we procured Valsartan from M/s Martin Dow Limited, Karachi only for development purpose (ADC invoice) attached for reference.* Here, we undertake that in future for commercialization of above product we will procure Valsartan from same source. The firm has submitted copy of invoice for the purchase of Valsartan (90Kg) attested by AD (I&E), Karachi dated 19-07-2016. <u>Amlodipine:</u> *We, M/s Martin Dow Marker limited apologize for mistakenly putting the wrong invoice in the dossier, the correct invoice is attached to this file.* The firm has submitted copy of invoice for the purchase of Amlodipine besylate (100Kg) attested by AD (I&E), Quetta dated 26-03-2019.
9.	Provide copy of Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMR of the stability batches for the drug product. *However, manufacturing date on BMR was 04-2020 while initially submitted stability data showed manufacturing date of 05-2019.* The firm again submitted that there is some typo error in BMR, so we will provide revised BMR accordingly.
10.	Submit updated copy of GMP certificate of drug substance manufacturer of Valsartan.	The firm has submitted copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration. It is valid till 10-04-2024.
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 7500/- fee for revision of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

491.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24848 Dated 08-09-2021
	Details of fee submitted	PKR 20,000/-: Dated: 07-07-2021

		PKR 10,000/-: Dated: 30-06-2021
	The proposed proprietary name / brand name	Lodopin-VHCT 5mg+160mg+25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine as Besylate……..5mg Valsartan……..…....160mg Hydrochlorothiazide….....25mg
	Pharmaceutical form of applied drug	Light Yellow, Oblong Biconvex film coated tablets on one side engraved with M-D and plan from another side
	Pharmacotherapeutic Group of (API)	Calcium channel blocker Angiotensin II receptor blocker (ARB) Thiazide diuretic (Anti-hypertensive)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge HCT 5/160/25 mg tablet by M/s Novartis Pharmaceuticals Corporation, USFDA Approved.
	For generic drugs (me-too status)	Exforge HCT 5/160/25 mg tablet by M/s Novartis (Pakistan) Limited, DRAP Approved.
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Name and address of API manufacturer.	**Amlodipine:** M/s Prudence Pharma chem, Plot No. 7407, Behind lakya lab, GIDC Ind. Estate, Ankleshwar -393 002 Dist. Bharuch, Gujarat, INDIA. **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co., Ltd. No. 6, North Airport Road, Sanazao Town, Jinwan District, Zhuhai City, Guangdong province, 519041, P.R. of China. **Hydrochlorothiazide:** M/s Changzhou Pharma, No.518 Laodong East Road, Changzhou, Jiangsu Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions:

		Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Real Time**: NPD-T-654-P, NPD-T-630-L, NPD-T-655-P **Accelerated Time:** NPD-T-654-P, NPD-T-630-L, NPD-T-655-P
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Exforge HCT 5/160/25 mg tablet by M/s Novartis Farmaceutica S.A., Barcelona Spain** by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is **Exforge HCT 5/160/25 mg tablet by M/s Novartis Farmaceutica S.A., Barcelona Spain** in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Amlodipine:** M/s Prudence Pharmachem, Gujarat (India) **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co. Ltd. China **Hydrochlorothiazide:** M/s Changzhou Pharmaceutical, China		
API Lot No.	**Amlodipine:** AMB/081/07/19 & AMB/082/07/19 **Valsartan:** 67819100605 **Hydrochlorothiazide:** EH180407		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Lodopin-VHCT 5mg+160mg+25mg Tablet			
Batch No.	NPD-T-654-P	NPD-T-630-L	NPD-T-655-P
Batch Size	10,000 Tablets	10,000 Tablets	10,000 Tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	04-2020	04-2020	04-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted registration letter of Glucovance Tablet 1000mg/5mg.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**M/s Prudence Pharmachem:** The firm has submitted copy of retention of license to manufacture for sale of drugs. License in Form-25, No No G/25/1656 has been retained from 08-04-2020 to 07-04-2025. **M/s Zhuhai Rundu:** Copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration has been submitted. It is valid till 10-04-2024. **M/s Changzhou Pharmaceutical:** GMP Certificate No JS20180848 issued by CFDA valid till 09-07-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine besylate:** The firm has submitted copy of invoice specifying import of Amlodipine besylate (Batch#AMB/082/04/19, 300Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 09-07-2019. **Valsartan:** The firm has submitted copy of invoice specifying import of Valsartan (Batch#67819100605, 150Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 26-02-2020. **Hydrochlorothiazide:** The firm has submitted copy of invoice specifying import of Hydrochlorothiazide (EH180407, 15Kg) attested by Assistant Director (I &E) DRAP, Quetta dated 02-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted audit trail record for dissolution and assay testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No	Observations communicated	Response by the firm
1.	The label claim of applied formulation does not define the equivalency of salt form of amlodipine besylate. Corrrection / clarification is required.	The firm has corrected the label claim of amlodipine besylate in applied formulation.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted method verification study of testing method of Lodopin VHCT Tablet by performing parameters like precision, linearity and accuracy.
3.	The reference literature shows that inactive ingredients for all strengths of the tablets include microcrystalline cellulose; crospovidone; colloidal anhydrous silica; magnesium stearate; hypromellose, macrogol 4000 and talc. Justify your formulation development in line with innovator product without addition of Hypromellose, macrogol 4000 and talc.	The firm replied that some of the excipients are not being used in the formulation like, Hypromellose, Macrogol 4000 & Talc. The mentioned excipients are used for coating purpose only. Therefore, we have used the ready-made film coating materials to make the film process simpler, easier to automate and enhances the elegance and glossy appearance of the coated tablets.
4.	Clarify the use of nomenclature process performance qualification protocol instead of adopting process validation protocol.	The firm has submitted process validation protocol of Lodopin VHCT Tablets.

5.	Justify why accuracy parameter was not studied in analytical method validation study for assay testing of drug product. Moreover, results of analytical method validation studies are required to be tabulated properly for Module 3.	The firm has submitted analytical method validation studies of testing method of Lodopin VHCT Tablet by performing linearity, accuracy precision.
6.	In this section, only summary of batch analysis release results of two batches has been submitted. Provide complete analysis details of two batches for which stability study has been conducted.	Complete analysis details of three batches has been submitted.
7.	The results of batch analysis and stability data reflect that test of uniformity of dosage unit has not been performed.	The firm has submitted performance of content uniformity test by individual assay of 10 tablets of Lodopin VHCT tablets for each amlodipine as besylate, valsartan and hydrochlorothiazide by HPLC.
8.	Justify the manufacturing of stability batches on 05-2019 since amlodipine besylate and Valsartan are cleared on 07-2019 and 02-2020, respectively as per the documents for import of drug substances submitted.	Valsartan: The firm has submitted that M/s. Martin Dow Marker Limited & M/s. Martin Dow limited perform function under the umbrella of Martin Dow group (same management). *So, when we were developing formulation of Lodopin VHCT in May 2019 at Martin Dow Marker limited, 7-Jail road Quetta, we procured Valsartan from M/s Martin Dow Limited, Karachi only for development purpose (ADC invoice) attached for reference.* Here, we undertake that in future for commercialization of above product we will procure Valsartan from same source. The firm has submitted copy of invoice for the purchase of Valsartan (90Kg) attested by AD (I&E), Karachi dated 19-07-2016. Amlodipine: *We, M/s Martin Dow Marker limited apologize for mistakenly putting the wrong invoice in the dossier, the correct invoice is attached to this file.* The firm has submitted copy of invoice for the purchase of Amlodipine besylate (100Kg) attested by AD (I&E), Quetta dated 26-03-2019.
9.	Provide copy of Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of BMR of the stability batches for the drug product. *However, manufacturing date on BMR was 04-2020 while initially submitted stability data showed manufacturing date of 05-2019.* The firm again submitted that there is some typo error in BMR, so we will provide revised BMR accordingly.
10.	Submit updated copy of GMP certificate of drug substance manufacturer of Valsartan.	The firm has submitted copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co. Ltd., China issued by China Food and Drug Administration. It is valid till 10-04-2024.
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers.

Decision: Approved.

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

• **Registration Board further decided that registration letter will be issued after submission of 7500/- fee for revision of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
492.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Private Limited., 44-45B Korangi creek road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited., 44-45B Korangi creek road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23538 Dated 27/08/2021
	Details of fee submitted	PKR 50,000/-: Dated 18-01-2021 PKR 25,000/- Dated: 26-07-2021
	The proposed proprietary name / brand name	Movcol Jar Powder for Solution 510g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains: Polyethylene glycol……..17g
	Pharmaceutical form of applied drug	White to off white color powder filled in HDPE bottle.
	Pharmacotherapeutic Group of (API)	Osmotic Laxative
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Miralax Powder 510g by M/s Bayer, USFDA Approved.
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New license granted on 07/10/2021 Sachet section (General) approved.
	Name and address of API manufacturer.	M/s Avesta Pharma pvt. Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Polyethylene glycol is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AP0912002, AP0912003 & AP0912004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Miralax 510g Jar by … Bayer by performing quality tests (Appearance, Identification, Filling weight, Moisture content & Assay). CDP is N/A
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s Avesta Pharma pvt. Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062, Maharashtra, India		
API Lot No.	AP0919009		
Description of Pack (Container closure system)	HDPE Bottles 1's		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 1, 2, 3, 4 & 6(Months) Real Time: 3, 6, 9 & 12 (Months)		
Batch No.	19SB-146-01	19SB-147-02	19SB-148-03
Batch Size	50 bottles	50 bottles	50 bottles
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	09-09-2019	09-09-2019	09-09-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s. Avesta Pharma Pvt. Ltd, Maharashtra state, India issued by Food and Drug Administration, Maharashtra state, India. It is valid upto 15-09-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software from Waters Corporation. Audit trail on testing of product has been submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. #	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report for Assay by GPC (HPLC). The parameters include specificity and system suitability, linearity, precision and accuracy parameters from drug substance manufacturer. Analytical method verification was also performed by drug product manufacturer.
2.	Evidence of approval of formulation in applied pack size i.e., 578g shall be required since bottle of three pack sizes mentioned in chemistry and biopharmaceutics review are 119g, 238g and 527g and unit dose foil pouch of 17g.	The firm has submitted evidence of approval of formulation in applied pack size. Unit dose compliance is achieved via measuring cap of the jar, which is engraved with the unit dose of 17g from inside.
3.	Scientific justification is required for not performing assay testing by HPLC method till 6-month time point in all batches and adopting HPLC method from 6 month onward.	Initially, we had performed stability studies at interval of 1,2,3,4 in spectrophotometric method. After purchasing RI Detector and column L 25 (Waters, Ultrahydrogel 120, 7.8 × 300 mm part No. WaT011520 Lot 002D190651). We had validated the method in HPLC. So 6th month interval and onward testing were conducted in HPLC.
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing records for all the batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance record of HPLC software from Waters Corporation.
6.	Documents for the procurement of drug substance with approval from DRAP is required.	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.

Decision: Deferred for following submissions:

- **Confirmation of required facility where manufacturing and packaging in Jar can be carried out.**
- **Clarification how the applied product is similar in terms of packaging material, unit dose and total dose per pack in comparison with the innovator's product.**
- **Evidence of HPLC system along with RI detector which is used for product testing.**

493.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23537 Dated 27-08-2021
	Details of fee submitted	PKR 50,000/-: Dated 18/01/2021 PKR 25,000/- Dated: 26/07/2021
	The proposed proprietary name / brand name	Movcol Jar Powder for Solution 765g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains: Polyethylene glycol……..17g
	Pharmaceutical form of applied drug	White to off white color powder filled in HDPE bottle.
	Pharmacotherapeutic Group of (API)	Osmotic Laxative
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Miralax Powder 765g by M/s Bayer, USFDA Approved.
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New license granted on 07/10/2021 Sachet section (General) approved.
	Name and address of API manufacturer.	AVESTA PHARMA PVT. LTD. Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Polyethylene glycol is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AP0912002, AP0912003 & AP0912004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Miralax 765g Jar by Bayer by performing quality tests (Appearance, Identification, Filling weight, Moisture content & Assay). CDP is N/A
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	AVESTA PHARMA PVT. LTD. Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra, India		
API Lot No.	AP0919009		
Description of Pack (Container closure system)	HDPE Bottles 1's		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 1, 2, 3, 4 & 6(Months) Real Time: 3, 6, 9 & 12 (Months)		
Batch No.	19SB-171-01	19SB-172-02	19SB-173-03
Batch Size	50 bottles	50 bottles	50 bottles
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	09-09-2019	09-09-2019	09-09-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s. Avesta Pharma Pvt. Ltd, Maharashtra state, India issued by Food and Drug Administration, Maharashtra state, India. It is valid upto 15-09-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software from Waters Corporation. Audit trail on testing of product has been submitted.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. #	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report for Assay by GPC (HPLC). The parameters include specificity and system suitability, linearity, precision and accuracy parameters from drug substance manufacturer. Analytical method verification was also performed by drug product manufacturer.
2.	Evidence of approval of formulation in applied pack size i.e., 578g shall be required since bottle of three pack sizes mentioned in chemistry and biopharmaceutics review are 119g, 238g and 527g and unit dose foil pouch of 17g.	The firm has submitted evidence of approval of formulation in applied pack size. Unit dose compliance is achieved via measuring cap of the jar, which is engraved with the unit dose of 17g from inside.
3.	Scientific justification is required for not performing assay testing by HPLC method till 6-month time point in all batches and adopting HPLC method from 6 month onward.	Initially, we had performed stability studies at interval of 1,2,3,4 in spectrophotometric method. After purchasing RI Detector and column L 25 (Waters, Ultrahydrogel 120, 7.8 × 300 mm part No. WaT011520 Lot 002D190651). We had validated the method in HPLC. So 6th month interval and onward testing were conducted in HPLC.
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing records for all the batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance record of HPLC software from Waters Corporation.
6.	Documents for the procurement of drug substance with approval from DRAP is required.	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.

Decision: Deferred for following submissions:

- **Confirmation of required facility where manufacturing and packaging in Jar can be carried out.**
- **Clarification how the applied product is similar in terms of packaging material, unit dose and total dose per pack in comparison with the innovator's product.**
- **Evidence of HPLC system along with RI detector which is used for product testing.**

494.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Private Limited., 44-45B Korangi creek road Karachi.
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited., 44-45B Korangi creek road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 23536 Dated 27/08/2021
	Details of fee submitted	PKR 50,000/-: Dated 18-01-2021 PKR 25,000/- Dated: 26-07-2021
	The proposed proprietary name / brand name	Movcol Jar Powder for Solution 119g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains: Polyethylene glycol……..17g
	Pharmaceutical form of applied drug	White to off white color powder filled in HDPE bottle.
	Pharmacotherapeutic Group of (API)	Osmotic Laxative
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Miralax Powder 119g by M/s Bayer, USFDA Approved.
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New license granted on 07/10/2021 Sachet section (General) approved.
	Name and address of API manufacturer.	AVESTA PHARMA PVT. LTD. Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Polyethylene glycol is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AP0912002, AP0912003 & AP0912004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Miralax 119g Jar by …

		Bayer by performing quality tests (Appearance, Identification, Filling weight, Moisture content & Assay). CDP is N/A
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	AVESTA PHARMA PVT. LTD. Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra, India		
API Lot No.	AP0919009		
Description of Pack (Container closure system)	HDPE Bottles 1's		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 1, 2, 3, 4 & 6(Months) Real Time: 3, 6, 9 & 12 (Months)		
Batch No.	19SB-133-01	19SB-134-02	19SB-135-03
Batch Size	50 bottles	50 bottles	50 bottles
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	09-09-2019	09-09-2019	09-09-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s. Avesta Pharma Pvt. Ltd, Maharashtra state, India issued by Food and Drug Administration, Maharashtra state, India. It is valid upto 15-09-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software from Waters Corporation. Audit trail on testing of product has been submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. #	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by	The firm has submitted analytical method verification report for Assay by GPC (HPLC). The parameters include specificity and system suitability,

	the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	linearity, precision and accuracy parameters from drug substance manufacturer. Analytical method verification was also performed by drug product manufacturer.
2.	Evidence of approval of formulation in applied pack size i.e., 578g shall be required since bottle of three pack sizes mentioned in chemistry and biopharmaceutics review are 119g, 238g and 527g and unit dose foil pouch of 17g.	The firm has submitted evidence of approval of formulation in applied pack size. Unit dose compliance is achieved via measuring cap of the jar, which is engraved with the unit dose of 17g from inside.
3.	Scientific justification is required for not performing assay testing by HPLC method till 6-month time point in all batches and adopting HPLC method from 6 month onward.	Initially, we had performed stability studies at interval of 1,2,3,4 in spectrophotometric method. After purchasing RI Detector and column L 25 (Waters, Ultrahydrogel 120, 7.8 × 300 mm part No. WaT011520 Lot 002D190651). We had validated the method in HPLC. So 6th month interval and onward testing were conducted in HPLC.
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing records for all the batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance record of HPLC software from Waters Corporation.
6.	Documents for the procurement of drug substance with approval from DRAP is required.	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.

Decision: Deferred for following submissions:

- **Confirmation of required facility where manufacturing and packaging in Jar can be carried out.**
- **Clarification how the applied product is similar in terms of packaging material, unit dose and total dose per pack in comparison with the innovator's product.**
- **Evidence of HPLC system along with RI detector which is used for product testing.**

495.	Name, address of Applicant / Marketing Authorization Holder	M/s Cunningham Pharmaceuticals (Pvt.) Ltd. Plot No. 81, Sunder industrial Estate Raiwind Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Ltd. Plot No. 81, Sunder industrial Estate Raiwind Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33172 Dated 21-12-2021
	Details of fee submitted	PKR 20,000/-: Dated 11-03-2020
	The proposed proprietary name / brand name	NU-ORS Sachet (Orange Flavor)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet Contains: Sodium chloride……...2.60gm

		Potassium chloride……..….1.50gm Tri-sodium citrate dihydrate…....2.90gm Dextrose anhydrous……..13.50gm
	Pharmaceutical form of applied drug	Granule to be reconstituted for oral administration
	Pharmacotherapeutic Group of (API)	Oral Rehydration Salts
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1 x 20's Sachets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	WHO Approved.
	For generic drugs (me-too status)	OEM Orange Flavour, Indus Pharma Karachi (Reg # 067312)
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. The firm has provided sachet section.
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Dominion salt Ltd., Totara street, Mount Maunganui, New Zealand. **Potassium Chloride:** M/s K+S KALI GmbH Germany, Am Kaliwerk 6, 36119 Neuhof, Germany **Trisodium Citrate:** M/s. Weifang Ensign Industry Co., Ltd. No. 1567, Changsheng Street, Changle, Weifang, shandong province, China. **Dextrose Anhydrous:** M/s Xiwang pharmaceutical., No. 237, Tongfu Road, Handian Town, Zouping Country, Binzhou city, Shandong Province, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance is submitted. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Official monograph of oral rehydration salts is present in BP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances.

	Stability studies	**Sodium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. **Potassium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. **Trisodium citrate dihydrate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months. **Glucose anhydrous:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III (Drug Product):	The firm has submitted details of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product OEM (ORS) orange flavour (Batch # OR-4043) by M/s Indus Pharma, Karachi by performing quality tests (Description, LOD, Average weight and Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision and specificity.

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Dominion salt Ltd., Totara street, Mount Maunganui, New Zealand. **Potassium Chloride:** M/s K+S KALI GmbH Germany, Am Kaliwerk 6, 36119 Neuhof, Germany **Tri Sodium Citrate:** M/s. Weifang Ensign Industry Co., Ltd. No. 1567, Changsheng Street, Changle, Weifang, shandong province, China. **Dextrose Anhydrous:** M/s Xiwang pharmaceutical., No. 237, Tongfu Road, Handian Town, Zouping Country, Binzhou city, Shandong Province, P.R. China.
API Lot No.	Sodium Chloride: 24042018 Potassium Chloride: 711800743 Trisodium Citrate: ST1803283

	Glucose Anhydrous (Dextrose): 211901315		
Description of Pack (Container closure system)	Aluminium Foil Sachets packed in unit carton (1×20's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	OT001	OT002	OT003
Batch Size	200 Sachet	200 Sachet	200 Sachet
Manufacturing Date	10-2019	10-2019	11-2019
Date of Initiation	07-10-2019	09-10-2019	07-11-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** The firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt Limited, New Zealand issued by Ministry of health, New Zealand. The certificate is valid till 29-07-2021. **Potassium Chloride:** The firm has submitted copy of GMP certificate of M/s K+S Kali GmbH issued by Regierungsprasidium, Darmstadt Germany. The certificate is valid till 06-03-2021. **Tri Sodium Citrate:** The firm has submitted document of verification of compliance certificate of M/s Weifang Ensign Industry Co., Ltd., China issued by SGS-CSTC Standards Technical services Co. ltd. The certificate is valid till 28-06-2024. **Dextrose Anhydrous:** Firm has submitted copy of GMP certificate (No. SD2020170644) of M/s Xiwang Pharmaceutical Co., ltd. China issued by China Food and Drug Administration. The certificate is valid till 11-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of sodium chloride dated 17-09-2019. **Potassium Chloride:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of potassium chloride dated 17-09-2019. **Tri Sodium Citrate:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of sodium citrate dated 17-09-2019. **Dextrose Anhydrous:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of Dextrose anhydrous dated 17-09-2019.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not applicable.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm
1.	Copy of GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	The firm has submitted request for renewal of GMP certificate to Director General (E & M), Lahore.
2.	Submit data of verification of analytical procedure of each drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted."*	The firm has submitted analytical method verification studies for each drug substance.
3.	Submit evidence of availability of atomic emission spectroscopy / flame photometer which is required in the testing of the drug product as per BP monograph.	The firm has submitted copy of invoice for the purchase of Flame photometer (Model: PFP7) from Western Analytical services dated 06-11-2019 (Invoice # 01119/097).
4.	Submit evidence of purchase / import documents of each drug substance.	**Sodium Chloride:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of sodium chloride dated 17-09-2019. **Potassium Chloride:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of potassium chloride dated 17-09-2019. **Tri Sodium Citrate:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of sodium citrate dated 17-09-2019. **Dextrose Anhydrous:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of Dextrose anhydrous dated 17-09-2019.

Decision: Registration Board referred the case to QA & LT division seeking opinion regarding use of API imported by the indentor not having valid DML.

496.	Name, Address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd, Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd, Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.17785: Dated 25-06-2021
	Details of fee submitted	PKR 30,000/-: Dated 10-06-2021
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 23-04-2019.
	The proposed proprietary name / brand name	Colicraft Injection I.V 2MIU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium……..……..2MIU
	Pharmaceutical form of applied drug	Glass vial filled with almost white to off-white colored Lyophilized Powder for Injection.
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Colistimethate sodium for injection of M/s Mukhtar Enterprises Lahore (Reg#094757).
	For generic drugs (me-too status)	Colistimethate sodium 2 MIU, powder for solution for injection by M/s PANMEDICA (MHRA Approved).
	Name and address of API manufacturer.	M/s Mac-Chem Products (India) Pvt. Ltd., N-211/2/10, MIDC. Boisar, District –Thane, Pin – 401 506, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	The firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2 °C / /65% ± 5%RH RH for 12 months Accelerated: 40°C ± 2°C /75% ± 5%RH for 6 months

		Batches: (CLS0219006, CLS0219008, CLS0219009).
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence of trial formulation (Batch # T001) against reference product Colistimethate Sodium 2MIU Injection (Lot No. 3056579) of M/s Xellia Pharmaceuticals by performing Biological assay by zone of inhibition method.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Mac-Chem Products (India) Pvt. Ltd., N-211/2/10, MIDC. Boisar, District –Thane, Pin – 401 506, Maharashtra, India.		
API Lot No.	CLS0218009		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 ,9,12,18,24 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Vials	1000 Vials	1000 vials
Manufacturing Date	08-2018	08-2018	08-2018
Date of Initiation	12-08-2018	14-08-2018	16-08-2018
No. of Batches	03		

DOCUMENTS / DATA REQUIRED ALONGWITH APPLICATION

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/74238/2018/11/24897 issued by Food and Drug Administration, Maharashtra State, India valid till 10-09-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (Invoice # 67533/2020 dated 27-01-2020 with received quantity of 5Kg) for the purchase of Colistimethate sodium for Injection. The invoice is cleared by Assistant director (I & E), DRAP, Islamabad.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N.A.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted Bioassay test method validation protocol and reports for the determination of colistimethate sodium by performing accuracy, precision, Linearity, range, ruggedness and specificity parameters.
2.	Valid copy of GMP certificate of drug substance manufacturer issued by country of origin.	
3.	COA of primary / secondary reference standard including source and lot number shall be provided.	The firm has submitted certificate of analysis showing working standard calibration report.
4.	Submit master formulation including theoretical fill weight per vial.	The firm has submitted master formulation showing quantity of fill weight per vial.
5.	Justify why pharmaceutical equivalence studies do not include all the tests as recommended by USP. Instead the test for microbiological has been performed only.	Firm has submitted revised pharmaceutical equivalence against reference product Colistimethate Sodium 2MIU Injection (Lot No. 3056579) of M/s Xellia Pharmaceuticals by performing identification, pH, uniformity of dosage unit, particulate matter, Biological assay, sterility and Endotoxin.
6.	Scientific justification of manufacturing of applied formulation by way of lyophilization using pre-lyophilized Colistimethate for Injection from M/s Mac-Chem Products (India) Pvt. Ltd.	The firm has submitted that the bulk and raw material of colistimethate sodium was available in lyophilized powder form. The raw material is then formulated into solution which is filled and lyophilized.
7.	Provide detailed method of analysis of the drug product instead of providing copy of USP monograph.	The firm has submitted method of analysis of the drug product.
8.	Provide detailed protocols how validation of analytical procedures of the drug product was carried out and further justify how the recovered concentration (mg/ml) was calculated in accuracy and recovery.	The firm has submitted Bioassay test method validation protocol and reports for the determination of colistimethate sodium. Accuracy is determined by standard addition method, previously analyzed sample with concentration of 0.2mg/ml were spiked with 50, 100, and 150% API and the mixtures were analyzed by the proposed method.
9.	Provide COA of reference standard actually used in the analysis of drug product.	The firm has submitted copy of USP primary reference standard with lot no. H3J047.
10.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of batch manufacturing records for all the batches of drug product for which stability studies data is provided.

Decision: Deferred for following submissions:

- **Valid GMP certificate or DML of drug substance manufacturer issued by relevant regulatory authority of the country of origin since submitted GMP certificate was valid till 10-9-2021.**

• **Scientific justification for using prelyophilized drug substance for formulation of the finished drug product by way of lyophilization.**		
497.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 28-08-2020
	Dy. No. and Date of submission	Dy. No. 23869 Dated 31-08-2021
	Details of fee submitted	PKR 50,000/-: Dated 01-04-2021 Balance fee: PKR 25,000/-: Dated 31-07-2021
	The proposed proprietary name / brand name	**BALOXA 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Baloxavir Marboxil…….……10mg
	Pharmaceutical form of applied drug	White to pale yellow white granules
	Pharmacotherapeutic Group of (API)	Anti-viral ATC Code: J05AX25
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xofluza granules 2% Sachet by M/s. Shionogi & Co Ltd, Japan (PMDA Approved)
	For generic drugs (me-too status)	Not applicable
	Name and address of API manufacturer.	M/s Fujian Jinshan Zhundian Pharmaceutical Co.,Ltd. Jintang Industry zone, Shaown city, Fujian Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C±2˚C/65%± 5%RH for 24 months Accelerated: 40˚C±2˚C/75%±5%RH for 6 months Batches: (180801, 180802, 180803)
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of the drug product.
	Pharmaceutical equivalence and comparative dissolution profile	It may please be noted that despite of our contacting M/s Genetech and Shionagi, we could not obtain required number of sachets for conducting comparative dissolution profile and Pharmaceutical equivalence. Since Xofluza 2% granules are neither available in the local market, nor could be procured from abroad nor is mentioned in any pharmacopeia, we have considered and ensured the quality parameters which give us the confidence that in-vitro parameter of our product is comparable with the innovator. Formulation of our product is qualitatively similar to innovator product.
	Analytical method validation/validation of product	Method validation studies have been submitted including linearity, accuracy, precision (repeatability and intermediate), robustness and specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fujian Jinshan Zhundian Pharmaceutical Co. Ltd., Address: Jintang Industry Zone, Shaowu City, Fujian Province, China		
API Lot No.	200101		
Description of Pack (Container closure system)	Aluminum Foil (Unprinted Triplex)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-1	Lab-2	Lab-3
Batch Size	1000 sachet	1000 sachet	1000 sachet
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	16-11-2020	16-11-2020	16-11-2020
No. of Batches	03		

DOCUMENTS / DATA REQUIRED ALONGWITH APPLICATION		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "RECADA (Racecadotril) 10mg & 30mg Sachet" which was presented in 290th meeting of

		Registration Board wherein the Board decided to approve registration of this product. Date of inspection: 10th May, 2019 According to inspection report, following points were confirmed: • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available. • Adequate monitoring and control are available for stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. FJ20160009 issued by Food and Drug Administration of China valid till 22-02-2021. As per Chinese Government website no more GMP certificates are being issued after December 2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (Invoice#WIS200028 dated March 18, 2020 with received quantity of 300gm) for the purchase of Baloxavir marboxil from M/s Fujian Jinshan Zhundian Pharmaceutical Co. Ltd., Jintand Industry zone, Shaown city, Fujian Province, China with attestation of DRAP dated 31st March 2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Observations communicated	Response by the firm
1.	Valid copy of DML / GMP certificate of API manufacturer issued by concerned regulatory authority shall be submitted.	As per the current law of People's Republic of China of the administration of the drug, the GMP and GSP certificates of medicine have been cancelled and will no longer be issued from December 1 2019. This notice can be verified on their website online link is below: http://english.nmpa.gov.cn/2019-11/29/c_456284.htm
2.	Elaborate the manufacturing process and method by which Baloxavir granules have been prepared in Section 3.2.P.2.	The chosen method of preparation is dry mixing. The manufacturing steps comprises of well-known processes like dispensing, sieving, blending, sieving, blending, filling and packaging. The process is considered to be the standard manufacturing process. In processes, controls are adequate for these types of manufacturing processes.
3.	Justify the product development studies without performing pharmaceutical equivalence and CDP studies with innovator/ reference product.	The reference product is not available in Japan. We have tried to arrange it from the country of origin but unfortunately not succeeded. Please also note that our formulation is similar to the innovator in the following, 1. API: Same as that of Reference listed drug.

		2. Dosage form: Same as that of Reference listed drug. 3. Indication: Same as that of Reference listed drug. 4. Excipients: Same as that of Reference listed drug. 5. Label claim: Same as that of Reference listed drug. However, for assay, dissolution and other chemical / microbiological attributes, we have tested the product according to the general guidelines of FDA and USP and complied. In 295th DRB meeting of DRAP Registration Board, same case of M/s. PharmEvo (pvt.) Limited was discussed and approved by Drug Registration Board. The product named Treow (Trelagliptin) 50mg Tablet and Treow (Trelagliptin) 100mg Tablet in which the firm did not perform comparative dissolution profile against innovator because they were unable to arrange the innovator packs from Japan without Japanese prescription which is only available in Japan.
4.	Justification is required for adopting the two time point study for dissolution test. Moreover, provide the basis for selection of dissolution test conditions.	The firm replied that we have adopted the two time point dissolution test from 293rd meeting minutes of DRAP *"Guidance document for Setting Dissolution Specifications of Immediate Release Solid Oral Dosage Form"* and from FDA guideline *"Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms"* which states that *"For slowly dissolving or poorly water soluble drugs (BCS class 2), a two-point dissolution specification, one at 15 minutes to include a dissolution range (a dissolution window) and the other at a later point (30, 45, or 60 minutes) to ensure 85% dissolution, is recommended to characterize the quality of the product".*

Decision: Deferred for following submissions:

- **Valid GMP certificate or DML of drug substance manufacturer issued by relevant regulatory authority of the country of origin since submitted GMP certificate was valid till 22-02-2021.**
- **Pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product.**

Case No.07: Registration applications of local manufacturing of human drugs submitted on CTD format

a. Deferred Cases

498.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	The firm is inspected on 02-07-2020 wherein the firm was found to be operating at good level of GMP compliance.
	Evidence of approval of manufacturing facility	The firm has provided Sachet (General) section from confirmed from approved layout plan from licensing division.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7172: 04-03-2021
	Details of fee submitted	PKR 50,000/-: 25-01-2021
	The proposed proprietary name / brand name	Movcol Jar 238g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains: Polyethylene glycol 3350…….17g
	Pharmaceutical form of applied drug	White to off white color powder filled in HDPE bottle.
	Pharmacotherapeutic Group of (API)	Osmotic laxative
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	1's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Miralax for oral solution of M/s Bayer Healthcare LLC (USFDA Approved, over the counter)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s Avesta Pharma Pvt Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has performed pharmaceutical equivalence of Movcol 238g Jar (B#19SB-143-01) of M/s Genix pharma with Miralax 238g Jar (B # 0C20PU) of M/s Bayer. Quality tests of both products including description, identification, filled weight, moisture content and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Avesta Pharma Pvt Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra India.		
API Lot No.	AP0919009		
Description of Pack (Container closure system)	HDPE Bottle		
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Movcol Jar 238g			
Batch No.	19SB-143-01	19SB-144-02	19SB-145-03
Batch Size	50 Bottles	50 Bottles	50 Bottles
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	09-09-2019	09-09-2019	09-09-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s. Avesta Pharma PVT LTD, Maharashtra state, India

		issued by Food and Drug Administration, Maharashtra state, India. It is valid upto 15-09-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance record of HPLC software from Waters Corporation. Audit trail of testing of product has not been submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Sr. No.	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report for Assay by GPC (HPLC). The parameters include specificity and system suitability, linearity, precision and accuracy parameters from drug substance manufacturer. Analytical method verification was also performed by drug product manufacturer.
2.	Evidence of approval of formulation in applied pack size i.e., 578g shall be required since bottle of three pack sizes mentioned in chemistry and biopharmaceutics review are 119g, 238g and 527g and unit dose foil pouch of 17g.	The firm has submitted evidence of approval of formulation in applied pack size. Unit dose compliance is achieved via measuring cap of the jar, which is engraved with the unit dose of 17g from inside.
3.	Scientific justification is required for not performing assay testing by HPLC method till 6-month time point in all batches and adopting HPLC method from 6 month onward.	Initially, we had performed stability studies at interval of 1,2,3,4 in spectrophotometric method. After purchasing RI Detector and column L 25. (Waters, Ultrahydrogel 120, 7.8 × 300 mm part No. WaT011520 Lot 002D190651). We had validated the method in HPLC. So 6th month interval and onward testing were conducted in HPLC.
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing records for all the batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance record of HPLC software from Waters Corporation.
6.	Documents for the procurement of drug substance with approval from DRAP is required.	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.

Registration Board deferred the case for following (M-313):

Sr.#	Decision of 316th meeting	Response by the firm
1.	Scientific justification of using Jar container closure system instead of using foil pouch as per reference product i.e., Miralax of M/s	The firm has submitted that we have used same container closure system as per reference product Miralax by M/s Bayer. It is available in jar in which

	Bayer for achieving unit dose dispensing of applied product.	unit dose compliance is achieved via measuring cap of the jar, engraved with the unit dose of 17g from inside.
2.	Evidence of availability of drug product in applied container closure system in reference regulatory authorities.	Miralax jar is also available in applied pack size of 238g jar in the same container closure system.

Decision: Deferred for following submissions:

- **Confirmation of required facility where manufacturing and packaging in Jar can be carried out.**
- **Clarification how the applied product is similar in terms of packaging material, unit dose and total dose per pack in comparison with the innovator's product.**
- **Evidence of HPLC system along with RI detector which is used for product testing.**

499.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm is inspected on 02-07-2020 wherein the firm was found to be operating at good level of GMP compliance.
	Evidence of approval of manufacturing facility	The firm has provided Sachet (General) section from confirmed from approved layout plan from licensing division.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7173: 04-03-2021
	Details of fee submitted	PKR 50,000/-: 04-06-2021
	proposed proprietary name / brand name	Movcol Jar 578g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains: Polyethylene glycol 3350…….17g
	Pharmaceutical form of applied drug	White to off white color powder filled in HDPE bottle.
	Pharmacotherapeutic Group of (API)	Osmotic laxative
	Reference to Finished product specification	Manufacturer's specifications
	Proposed Pack size	1's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Miralax for oral solution of M/s Bayer Healthcare LLC (USFDA Approved, over the counter)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s Avesta Pharma Pvt Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai–400 062 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has performed pharmaceutical equivalence and comparative dissolution profile of Movcol 578g Jar (B#19SB-149-01) and Miralax 578g Jar (B # TN00RM) of M/s Bayer. Quality tests of both products including description, identification, filled weight, moisture content and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Avesta Pharma Pvt Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra India.
API Lot No.	AP0919009
Description of Pack (Container closure system)	HDPE Bottle
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Movcol Jar 578g			
Batch No.	19SB-149-01	19SB-150-02	19SB-151-03
Batch Size	50 Bottles	50 Bottles	50 Bottles
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	09-09-2019	09-09-2019	09-09-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s. Avesta Pharma Pvt. Ltd, Maharashtra state, India issued by Food and Drug Administration, Maharashtra state, India. It is valid upto 15-09-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance record of HPLC software from Waters Corporation. Audit trail of testing of product has not been submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S#	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report for Assay by GPC (HPLC). The parameters include specificity and system suitability, linearity, precision and accuracy parameters from drug substance manufacturer. Analytical method verification was also performed by drug product manufacturer.
2.	Evidence of approval of formulation in applied pack size i.e., 578g shall be required since bottle of three pack sizes mentioned in chemistry and biopharmaceutics review are 119g, 238g and 527g and unit dose foil pouch of 17g.	The firm has submitted evidence of approval of formulation in applied pack size. Unit dose compliance is achieved via measuring cap of the jar, which is engraved with the unit dose of 17g from inside.
3.	Scientific justification is required for not performing assay testing by HPLC method till 6-month time point in all batches and adopting HPLC method from 6 month onward.	Initially, we had performed stability studies at interval of 1,2,3,4 in spectrophotometric method. After purchasing RI Detector and column L 25 (Waters, Ultrahydrogel 120, 7.8 × 300 mm part No. WaT011520 Lot 002D190651). We had validated the method in HPLC. So 6th month interval and onward testing were conducted in HPLC.
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for	The firm has submitted copy of batch manufacturing records for all the batches.

	which stability studies data is provided in Module 3 section 3.2.P.8.3.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance record of HPLC software from Waters Corporation.
6.	Documents for the procurement of drug substance with approval from DRAP is required.	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.

Deferred for following submission:

Sr.#	Decision of 316th meeting	Response by the firm
1.	Scientific justification of using Jar container closure system instead of using foil pouch as per reference product i.e., Miralax of M/s Bayer for achieving unit dose dispensing of applied product.	The firm has submitted that we have used same container closure system as per reference product Miralax by M/s Bayer. It is available in jar in which unit dose compliance is achieved via measuring cap of the jar, engraved with the unit dose of 17g from inside.
2.	Evidence of availability of drug product in applied container closure system in reference regulatory authorities.	Miralax jar is also available in applied pack size of 578g jar in the same container closure system.

Decision: Deferred for following submissions:

- **Confirmation of required facility where manufacturing and packaging in Jar can be carried out.**
- **Clarification how the applied product is similar in terms of packaging material, unit dose and total dose per pack in comparison with the innovator's product.**
- **Evidence of HPLC system along with RI detector which is used for product testing.**

500.	Name, address of Applicant / Marketing Authorization Holder	M/s Vision Pharmaceuticals (Pvt.) Ltd., Plot # 22-23, Industrial triangle, kahuta road, Islamabad-44000.
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23, Industrial triangle, kahuta road, Islamabad-44000.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 25/02/2019 The firm has provided Liquid Ampoule General section.
	Dy. No. and date of submission	Dy. No. 17243: Dated 02-06-2021
	Details of fee submitted	PKR 30,000/-: Dated 28-05-2021
	The proposed proprietary name / brand name	Vision DS Injection 600mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml contains: Lincomycin as hydrochloride…….600mg
	Pharmaceutical form of applied drug	Clear to slightly yellow colour liquid injection
	Pharmacotherapeutic Group of (API)	Antibiotics
	Reference to Finished product specifications	USP specifications

	Proposed Pack size	10's, 50's & 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LINCOMYCIN SXP 600mg/2ml solution for injection ampoule by M/s Southem XP IP Pty Ltd, (TGA Approved).
	For generic drugs (me-too status)	Olinc 600mg/2ml Injection by M/s Bosch Karachi, Reg. No. 025416
	Name and address of API manufacturer.	M/s Topfond Pharmaceutical Co., Ltd., No.2, Guangming Road, Zhumadian City, 463000, Henan P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65%±5%RH for 48 months Accelerated: 40°C ± 2°C /75%±5%RH for 6 months Batches: (081101, 081102, 081103)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted comparative assay data of trial formulation (Batch # NPD 213 T-01) against the comparator product Lincocin Injection (Batch # C151) by Sanofi – Aventis Pakistan Ltd. Karachi by performing quality tests (Physical appearance, Assay, pH, Liquid Particle Count).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Topfond Pharmaceutical Co., Ltd., No.2, Guangming Road, Zhumadian City, 463000, Henan P.R. China.
API Lot No.	1907025
Description of Pack	2 ml ampoule,

(Container closure system)	Type II glass		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	NPD213-T01	NPD213-T02	NPD213-T03
Batch Size	1587 Amp	1587 Amp	1587 Amp
Manufacturing Date	09-20	09-20	09-20
Date of Initiation	22-09-2020	22-09-2020	22-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to onsite inspection report of their product Calador 400mg/100ml Infusion which was conducted on 24-08-2021 and was presented in 312th meeting of Registration Board held on 14-16th September, 2021. According to the report following points were confirmed. •The firm has 21 CFR compliant HPLC software •The firm has audit trail reports available. The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. HA20160021 issued by CFDA valid till 17-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial Invoice to import Lincomycin HCl (Invoice # XX17026) dated Jul-28-2017 attested by AD (I & E) DRAP Islamabad dated 20-09-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

Sr.#	Observations communicated	Response by the firm
1.	Copies of the drug substance specification and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer.	Copies of the drug substance specification and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are attached.
2.	Submitted drug substance specifications are as per Indian Pharmacopoeia while monograph of drug substance is available in USP.	As we have used material by Topfond pharmaceutical Co. Ltd which is as per USP monograph. We have revised documents and complete DMF & QOS is attached here. Initially the firm had provided DMF from Henan Xinxiang Huaxing Pharmaceutical factory. However, the limits provided by FPP

		manufacturer for pH, specific optical rotation, water contents and assay are different from API manufacturer.
3.	Analytical method verification reports of parameters like specificity, accuracy & repeatability (method precision) performed by the drug product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Analytical method verification reports of parameters like specificity, accuracy & repeatability (method precision) performed by the drug product manufacturer are attached.
4.	Submitted certificate of analysis is from Topfond pharmaceutical Co. Ltd while drug substance manufacturer is M/s Henan Xinxiang Huaxing Pharmaceutical Factory.	API used for manufacturing & testing is by Topfond pharmaceutical Co. Ltd. accidently DMF of Henan Xinxiang Huaxing Pharmaceutical factory is provided in dossier.
5.	Reference standard was not from drug substance manufacturer.	Not submitted.
6.	Details of batch numbering of reference product and test formulation used for Pharmaceutical equivalence are required. Pharmaceutical equivalence should contain results of all the quality tests mentioned in official pharmacopoeia of the developed formulation and the reference product.	The firm has submitted comparative assay profile protocol as well as report of trial formulation with comparator product Linocin Injection 600mg/2ml. However, pharmaceutical equivalence results containing all the tests have not been submitted.
7.	In section 3.2.P.2.4, type II glass vial has been chosen as container closure system while in manufacturing process development glass ampoule has been mentioned	It is a typing error, container closure used is Glass ampoule
8.	Justification/Clarification is required regarding target fill weight of Lincomycin hydrochloride as 1031.0kg in batch formula for preparing 1587 ampoules.	It is error occurred during typing, the actual quantity dispensed is 1.031kg instead of 1031.0kg. As per trial card, the quantity dispensed is 1.119 Kg.
9.	Justification shall be submitted for not performing terminal sterilization in applied injection. Moreover, step of aseptic filling process has also not been mentioned.	The firm has submitted that we performed the autoclave on all trials. Highlighted trial card is also attached.
10.	Justify the weight taken for Lincomycin hydrochloride in different sets of accuracy parameter in analytical method validation studies. Moreover, basis for setting 100% theoretical contents are required to be clarified.	As per USP, standard concentration is 1.2 mg per ml, so we have prepared the sample also as 2ml containing 600mg of Lincomycin so we pipette 2 ml and transfer to 50ml volumetric flask. In second dilution, we transfer 5ml from it to another 50ml volumetric flask, making final concentration of 1.2mg / ml. For other concentration spiking was done as per protocol.
11.	Chromatograms of Lincomycin injection samples contain two principle peaks. Clarification is required for these two peaks	Chromatograms of Lincomycin injection samples contain two principle peaks. As this finished product only containing API (Lincomycin HCl) and excipient (Benzyl Alcohol) Peak at 16.443 minutes is of LINCOMYCIN and peak on 11.396 minutes is of BENZYL ALCOHOL. Secondly, 210nm of wavelength is used for analysis.

Deferred for following:

Sr.#	Decision of 316th meeting	Response by the firm
1.	Clarification of dispensed quantity of Lincomycin hydrochloride for manufacturing of 1587 ampoules of each trial batch since the quantity mentioned on master formulation is different from trial card.	The firm has submitted that the difference is just due to rounding off during calculation. For 3.3 L, the ampoules prepared should be 1571. While calculation, we take 3.33 L for which ampoules will be 1587.

		• Calculation of API per ampoule. 3.3 Liters = 3300ml. 3300ml x 300mg = 990000mg (600mg is present in 2ml so for 1 ml 300mg as mentioned above.) By converting mg to Kg. 990000mg / 1000 = 990 grams 990grams / 1000 = 0.99 Kg So, 0.99 x 100/88.51 = 1.1185 Kg By calculating for 2.1ml per ampoule the calculation is as below. 3300/2.1 = 1571 Ampoules Per Ampoule 600mg x 2.1/2 = 630mg 630 mg 100/88.51 = 711.78mg So, for 1571 Ampoules we will require API as 1571 Ampoules x 711.78mg = 1.1182 By rounding 1.1182 it becomes 1.119 Kg
2.	Provide COA of primary / secondary reference standard including source and lot number.	The firm has submitted copy of COA of working standard from drug substance manufacturer (M/s Topfond Pharmaceutical Co. Ltd) with lot number of 19070024.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further directed the firm to dispense the drug substance for commercial batch manufcaturing on the basis of actual potency of drug substance determined durinig drug substance analysis.**

501.	Name, address of Applicant / Marketing Authorization Holder	M/s Arsons Pharmaceutical Industries (Pvt) Ltd., 22 Km Multan Road off, 2.5 Km, Defence Road, Lahore
	Name, address of Manufacturing site.	M/s Arsons Pharmaceutical Industries (Pvt) Ltd., 22 Km Multan Road off, 2.5 Km, Defence Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the firm	The firm is granted GMP certificate based on inspection conducted on 18-09-2019.
	Dy. No. and date of submission	Dy. No. 17389 Dated 22-06-2021
	Details of fee submitted	PKR 30,000/-: Dated 07-06-2021
	The proposed proprietary name / brand name	Peflam 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Diclofenac potassium…….50mg
	Pharmaceutical form of applied drug	Light brown colored round biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	NSAIDs
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cataflam 50mg Tablet of M/s Novartis (USFDA approved)
	For generic drugs (me-too status)	Voltaflam Tablet of M/s Platinum pharma (Reg# 021621)
	Name and address of API manufacturer.	M/s Henan Dongtai Pharm Co. Ltd., East Changhong Road, Tangyin, Henan, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (131118-5, 131118-6, 131119-5)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted comparative dissolution studies Peflam 50mg Tablet (B#PF001) with comparator product Caflam 50mg tablet (B#PK3R) in three media pH 1.2, acetate buffer pH 4.5 and phosphate buffer pH 6.8.
	Analytical method validation/verification of product	Method validation studies have been submitted including accuracy, precision, robustness and specificity studies.

STABILITY STUDY DATA

Manufacturer of API	M/s Henan Dongtai Pharmaceutical Co. Ltd., No. 2, East Kangtai Road, Tangyin County, Anyang city, China.
API Lot No.	0303191005-5
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (2 × 10's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Peflam-50 Tablet			
Batch No.	PF-001	PF-002	PF-003
Batch Size	2100 Tablets	2100 Tablets	2100 Tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	09-01-2021	13-01-2021	15-01-2021
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (Certificate # HA20190077) of M/s Henan Dongtai Pharmaceutical Co., Ltd. China issued by He Nan Province Drug administration, China. It is valid till 05-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance record of HPLC software and audit trail record of product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr.#	Observations communicated	Response by the firm
1.	Copies of the drug substance specifications and analytical procedures used for routine testing of the drug substance / active pharmaceutical ingredient by both drug substance & drug Product manufacturer. Moreover, analytical procedure for assay testing has not been provided.	The firm has submitted that drug substance specifications are part of analytical procedure. The firm has submitted copies of analytical procedure from both drug substance and drug product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification protocol and reports for assay method by titration method. The verification study does not include accuracy and specificity parameters.
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by drug Product manufacturer used during product development and stability studies, along with certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.	The firm has submitted certificate of analysis of drug substance from both drug substance and drug product manufacturer.
4.	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.	The firm has provided comparative dissolution profile studies with Anti-flam Tablet 50mg. The performance of pharmaceutical equivalence studies with innovator product was not provided.

5.	Submit acceptance criteria for release and shelf life specifications.	The firm has submitted that release limit and shelf life specifications comply USP monograph. Both the limits are exactly the same.
6.	Justify method verification studies without performance of specificity studies. Moreover, relevant chromatograms for each studied parameter are required.	The firm has submitted performance of linearity and precision studies.
7.	Reference of previous approval of applications with stability study data of the firm (if any).	No approvals have been granted so far with stability studies, however, we have 21 CFR compliant HPLC alongwith audit trail enabled. Further our stability chambers are also attached with UPS and 24-h monitoring record.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (Certificate # HA20190077) of M/s Henan Dongtai Pharmaceutical Co., Ltd. China issued by HeNan Province Drug administration, China. It is valid till 05-11-2024.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.

Deferred for submission of following:

Sr.#	**Decision of 316th meeting**	**Response by the firm**
1.	Submission of complete analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted results of accuracy and specificity parameters alonwith relevant chromatograms.
2.	Justification for adopting same acceptance criteria for release and shelf life specifications.	The firm has not submitted any justification for adopting same acceptance criteria for release and shelf life specifications.
3.	Performance of pharmaceutical equivalence and CDP studies with innovator/reference product.	The firm has submitted comparative dissolution studies Peflam 50mg Tablet (B#PF001) with comparator product Caflam 50mg tablet (B#PK3R) in three media pH 1.2, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The performance of pharmaceutical equivalence studies was not provided.
4.	Analytical method verification protocol and reports of drug product as per requirements of section 3.2.P.5.3 of Form-5F.	The firm has submitted analytical method verification protocol and reports of drug product by performing system suitability, specificity, linearity, precision and accuracy parameters.
5.	Evidence of procurement of API with approval from DRAP.	The firm has submitted copy of invoice specifying import of Diclofenac potassium 1000 Kgs attested by Assistant Director (I & E), lahore dated 02-10-2019.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further deciced that registration letter will be issued upon subsmission of Pharmaceutical equivalence studies against the innovator product.**

502.	Name, address of Applicant / Marketing Authorization Holder	M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot # 22-23, Industrial triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**M/s Standpharm Pakistan:** Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML. **M/s Vision Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 23-04-2019.
	Evidence of approval of manufacturing facility	**M/s Vision Pharmaceuticals:** The firm has provided sterile Dry powder injection vials (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11788: 20-04-2021
	Details of fee submitted	PKR 50,000/-: 09-03-2021
	The proposed proprietary name / brand name	CISEC 40mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole sodium eq. to Omeprazole (as lyophilized powder) …….40mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion of M/s Sandoz Novartis (MHRA approved)
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma Pakistan
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and comparator product Risek Injection 40mg (B # 789P06) of M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of drug substance. Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot No.	1702901 1702902 1702903		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Rapid 40mg I.V Injection			
Batch No.	1803707	1803708	1803709
Batch Size	10,000 vials	10,000 vials	10,000 vials
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	03-2018	03-2018	03-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	Documents To Be Provided	Status

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad. It is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has procured material from their semi basic manufacturing facility.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail on testing reports of product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Sr. No.	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report from M/s Vision Pharmaceuticals Pvt, Ltd. Islamabad.
2.	Certificate of analysis of both drug substance manufacturer and drug product manufacturer are required.	The firm has submitted COAs of 3 batches of omeprazole lyophilized powder. The firm stated that we have a combined QC of both Formulation (000517) and Semi-Basic (000806) facility having same equipment and analysts for both facilities.
3.	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and Risek 40mg Injection (B # 789P06) manufactured by M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
4.	Scientific justification is required for performing assay testing by UV method instead of HPLC method.	As the stability studies of the Bulk lyophilized material is performed by the Bulk manufacturer in the same QC lab with the same instrument (on HPLC) so just for verification purpose we performed the stability of the said product by UV. The firm has not submitted stability study data performed by HPLC alongwith raw data sheets, chromatograms and summary data sheets.
5.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing record of 3 batches for which stability studies were carried out.
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Stability testing is performed by UV spectrophotometry therefore audit trail is not required.
7.	Documents for the procurement of drug substance with approval from DRAP is required.	We have procured omeprazole sodium lyophilized ready to fill powder our own Semi-basic facility.

8.	Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	The firm has not submitted the details of reconstitution diluents with which dilution was carried.
9.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Compatibility studies were not provided with required diluents.

Evaluation by PEC:

Sr. No.	Decision of 313th meeting of RB	Response by the firm
1.	Justification of adopting UV-visible spectrophotometric method for assay testing of applied formulation.	• As we have the facility for semi basic preparation & we are lyophilizing the omeprazole and conduct the testing on HPLC. • In Omeprazole 40 mg Injection (commercial batch) we are filling the same lyophilized powder tested in our quality control laboratory. • We performed the final month Stability testing on HPLC. Testing for 36th month is attached in Annexure I.
2.	Submission of results of in-use stability studies of the drug product to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	Testing after reconstitution shows satisfactory results **Reconstituted Diluent** / **Storage Condition** / **In-Use Shelf Life** NaCl 0.9% solution: 2 – 8 ºC: 24 Hours; 25 ºC: 12 Hours Testing Reports with brief summary of results are attached in Annexure II.
3.	Submission of compatibility studies for the dry powder for injections to be performed as per the instructions provided in individual label of the drug product.	Omeprazole Dry Powder for Injection in reconstituted with 10ml of NaCl 0.9% solution and shows satisfactory results after 8 hours under storage condition 2 – 8 ºC. Testing Reports are attached in Annexure III
4.	Capacity assessment of manufacturing and testing facility of M/s Vision Pharmaceuticals Pvt. Ltd.	Capacity Assessment of manufacturing and testing facility of M/s Vision Pharma has been carried out.

Decision: RegistrationBoard noted the fact that firm had initially submitted stability studies data by UV spectrophotometric method ofor Assay test, while HPLC method was adopted for the 36th month time point of long term stability studies hence Registration Board deferred the case for submission of batch release data of recently manufactured commercial batches by M/s Visio npharmaceuticals wherein assay testing shall be performed using HPLC method.

503.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan.
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot # 22-23, Industrial triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**M/s Carer pharmaceutical Industries:** The firm is granted new license on 18/03/2021.

		M/s Vision Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 23-04-2019.
	Evidence of approval of manufacturing facility	**M/s Vision Pharmaceuticals:** The firm has provided sterile Dry powder injection vials (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13450: 19-05-2021
	Details of fee submitted	PKR 50,000/-: 12-02-2021
	The proposed proprietary name / brand name	Desan 40mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole sodium eq. to Omeprazole (as lyophilized powder) …….40mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion of M/s Sandoz Novartis (MHRA approved)
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma Pakistan
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and Risek 40mg Injection (B # 789P06) manufactured by M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of drug substance. Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot No.	1702901 1702902 1702903		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Rapid 40mg I.V Injection			
Batch No.	1803707	1803708	1803709
Batch Size	10,000 vials	10,000 vials	10,000 vials
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	03-2018	03-2018	03-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad. It is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has procured material from their semi basic manufacturing facility.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail on testing reports of product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Sr. No.	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report from M/s Vision Pharmaceuticals Pvt, Ltd. Islamabad.
2.	Certificate of analysis of both drug substance manufacturer and drug product manufacturer are required.	The firm has submitted COAs of 3 batches of omeprazole lyophilized powder. The firm stated that we have a combined QC of both Formulation (000517) and Semi-Basic (000806) facility having same equipment and analysts for both facilities.
3.	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and Risek 40mg Injection (B # 789P06) manufactured by M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
4.	Scientific justification is required for performing assay testing by UV method instead of HPLC method.	As the stability studies of the Bulk lyophilized material is performed by the Bulk manufacturer in the same QC lab with the same instrument (on HPLC) so just for verification purpose we performed the stability of the said product by UV. The firm has not submitted stability study data performed by HPLC alongwith raw data sheets, chromatograms and summary data sheets.
5.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing record of 3 batches for which stability studies were carried out.
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Stability testing is performed by UV spectrometry therefore audit trail is not required.
7.	Documents for the procurement of drug substance with approval from DRAP is required.	We have procured omeprazole sodium lyophilized ready to fill powder our own Semi-basic facility.

8.	Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	The firm has not submitted the details of reconstitution diluents with which dilution was carried.
9.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Compatibility studies were not provided with required diluents.

Evaluation by PEC:

Sr. No.	**Decision of 313th meeting of RB**	**Response by the firm**
1.	Justification of adopting UV-visible spectrophotometric method for assay testing of applied formulation.	• As we have the facility for semi basic preparation & we are lyophilizing the omeprazole and conduct the testing on HPLC. • In Omeprazole 40 mg Injection (commercial batch) we are filling the same lyophilized powder tested in our quality control laboratory. • We performed the final month Stability testing on HPLC. Testing for 36th month is attached in Annexure I.
2.	Submission of results of in-use stability studies of the drug product to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	Testing after reconstitution shows satisfactory results **Reconstituted Diluent** / **Storage Condition** / **In-Use Shelf Life** NaCl 0.9% solution: 2 – 8 ºC: 24 Hours; 25 ºC: 12 Hours Testing Reports with brief summary of results are attached in Annexure II.
3.	Submission of compatibility studies for the dry powder for injections to be performed as per the instructions provided in individual label of the drug product.	Omeprazole Dry Powder for Injection in reconstituted with 10ml of NaCl 0.9% solution and shows satisfactory results after 8 hours under storage condition 2 – 8 ºC. Testing Reports are attached in Annexure III
4.	Capacity assessment of manufacturing and testing facility of M/s Vision Pharmaceuticals Pvt. Ltd.	Capacity Assessment of manufacturing and testing facility of M/s Vision Pharma has been carried out.

Decision: Deferred for submission of data of recently manufactured commercial batches in which assay testing has been performed using HPLC method.

504.	Name, address of Applicant / Marketing Authorization Holder	M/s Nagarsons Pharmaceuticals (Pvt) Ltd, Plot # 34, Street No. NS-2, National Industrial Zone, Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot # 22-23, Industrial triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the firm	**M/s Nagarsons Pharmaceuticals:** The firm is inspected on 23-05-2019 which concluded that overall GMP compliance could be graded as Good for visited sections as of today. The firm has provided 8 sections. **M/s Vision Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 23-04-2019.
	Evidence of approval of manufacturing facility	**M/s Vision Pharmaceuticals:** The firm has provided sterile Dry powder injection vials (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8314: 15-03-2021
	Details of fee submitted	PKR 50,000/-: 07-01-2021
	The proposed proprietary name / brand name	Nagzole 40mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole sodium eq. to Omeprazole (as lyophilized powder) …….40mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion of M/s Sandoz Novartis (MHRA approved)
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma Pakistan
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and comparator product (B # 789P06) of M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of drug substance. Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot No.	1702901 1702902 1702903		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Rapid 40mg I.V Injection			
Batch No.	1803707	1803708	1803709
Batch Size	10,000 vials	10,000 vials	10,000 vials
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	03-2018	03-2018	03-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad. It is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has procured material from their semi basic manufacturing facility.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail on testing reports of product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Sr. No.	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report from M/s Vision Pharmaceuticals Pvt, Ltd. Islamabad.
2.	Certificate of analysis of both drug substance manufacturer and drug product manufacturer are required.	The firm has submitted COAs of 3 batches of omeprazole lyophilized powder. The firm stated that we have a combined QC of both Formulation (000517) and Semi-Basic (000806) facility having same equipment and analysts for both facilities.
3.	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and Risek 40mg Injection (B # 789P06) manufactured by M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
4.	Scientific justification is required for performing assay testing by UV method instead of HPLC method.	As the stability studies of the Bulk lyophilized material is performed by the Bulk manufacturer in the same QC lab with the same instrument (on HPLC) so just for verification purpose we performed the stability of the said product by UV. The firm has not submitted stability study data performed by HPLC alongwith raw data sheets, chromatograms and summary data sheets.
5.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing record of 3 batches for which stability studies were carried out.
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Stability testing is performed by UV spectrometry therefore audit trail is not required.
7.	Documents for the procurement of drug substance with approval from DRAP is required.	We have procured omeprazole sodium lyophilized ready to fill powder our own Semi-basic facility.

8.	Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	The firm has not submitted the details of reconstitution diluents with which dilution was carried.
9.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Compatibility studies were not provided with required diluents.

Evaluation by PEC:

<table>
<tr><th>Sr. No.</th><th>Decision of 313th meeting of RB</th><th>Response by the firm</th></tr>
<tr><td>1.</td><td>Justification of adopting UV-visible spectrophotometric method for assay testing of applied formulation.</td><td>• As we have the facility for semi basic preparation & we are lyophilizing the omeprazole and conduct the testing on HPLC.
• In Omeprazole 40 mg Injection (commercial batch) we are filling the same lyophilized powder tested in our quality control laboratory.
• We performed the final month Stability testing on HPLC. Testing for 36th month is attached in Annexure I.</td></tr>
<tr><td>2.</td><td>Submission of results of in-use stability studies of the drug product to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.</td><td>Testing after reconstitution shows satisfactory results
<table>
<tr><th>Reconstituted Diluent</th><th>Storage Condition</th><th>In-Use Shelf Life</th></tr>
<tr><td rowspan="2">NaCl 0.9% solution</td><td>2 – 8 ºC</td><td>24 Hours</td></tr>
<tr><td>25 ºC</td><td>12 Hours</td></tr>
</table>
Testing Reports with brief summary of results are attached in Annexure II.</td></tr>
<tr><td>3.</td><td>Submission of compatibility studies for the dry powder for injections to be performed as per the instructions provided in individual label of the drug product.</td><td>Omeprazole Dry Powder for Injection in reconstituted with 10ml of NaCl 0.9% solution and shows satisfactory results after 8 hours under storage condition 2 - 8 ºC.</td></tr>
<tr><td>4.</td><td>Capacity assessment of manufacturing and testing facility of M/s Vision Pharmaceuticals Pvt. Ltd.</td><td>Capacity Assessment of manufacturing and testing facility of M/s Vision Pharma has been carried out.</td></tr>
</table>

Decision: RegistrationBoard noted the fact that firm had initially submitted stability studies data by UV spectrophotometric method ofor Assay test, while HPLC method was adopted for the 36th month time point of long term stability studies hence Registration Board deferred the case for submission of batch release data of recently manufactured commercial batches by M/s Visio npharmaceuticals wherein assay testing shall be performed using HPLC method.

Cases of New Sections & New License

505.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Hea Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. dated 11/04/2022
	Details of fee submitted	PKR 30,000/-: dated 28/03/2022
	The proposed proprietary name / brand name	Cef-Sulb Injection 1gm
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder Cefoperazone sodium MS equivalent Cefoperazone……..500mg Sterile Powder Sulbactam sodium MS equivalent Sulbactam…….500mg
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 1gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 1gm by Global Pharmaceuticals, Reg. N 042552
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Summarized information related to nomenclatur structure, general properties, solubilities, physical forn manufacturers, description of manufacturing process ar controls, impurities, specifications, analytical procedur and its verification, batch analysis and justification specification, reference standard, container closure syste and stability studies of drug substance and drug product submitted.
	Module III (Drug Substance)	Official monograph of Cefoperazone sodium /Sulbacta sodium eq to Cefoperazone /Sulbactam not present in ar pharmacopeia. The firm has submitted detail nomenclature, structure, general properties, solubilitie physical form, manufacturers, description of manufacturir

		process and controls, tests for impurity D, G & relate substances (impurity A & unspecified), specification analytical procedures and its verification, batch analys and justification of specification, reference standar container closure system and stability studies of dru substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (T-CSP001, T-CSP002, T-CSP003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, descriptio of manufacturing process and controls, impuritie specifications, analytical procedure (including dissolutio testing at acidic and buffer medium) and its verificatio studies, batch analysis and justification of specificatio reference standard, container closure system and stabili studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established again the brand leader that is Toxirid Injection 1gm by Glob Pharmaceuticals Pakistan performing quality tes (Identification, Assay, Constituted Solution, Uniformity dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted includin linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China		
API Lot No.	CEFP17/023/06/21		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leafl in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-CSP001	T-CSP002	T-CSP003
Batch Size (Scientifically rational batch size)	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	26-09-2021	26-09-2021	26-09-2021
No. of Batches	03		

Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20191025 issued by CFDA valid till 10/12/2024.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Letter No. 11160/2021/DRAP Dated: 27-07-2021 B/L No. 176-6445-291 dated: 31-07-2021

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

Shortcomings communicated to the Firm:

- You have mentioned USP specification in section 1.5.6 in module 1, while the drug product monograph is not availab in USP, but present in JP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both USP and in-house standards for the drug substance, provi scientific justification in this regard.
- Justify, how you have claimed USP specification for drug substance cefoperazone sodium+Sulbactum30-May- sodium, when the monograph has not been present in USP.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies th "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substan /Active Pharmaceutical Ingredient by both Drug substance manufacturers."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states th "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) perform by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall submitted". Further justify how the analysis of drug substance was conducted without performing verification studi of the analytical method of drug substance.
- Stability study data of 3 batches of drug substances till the assigned shelf life needs to be submitted, since stability da of 3 months has submitted despite the batch had been manufactured in 2017.
- Submit data in section 3.2.P.1 (c) as per the decision of 293rd meeting of Registration Board, which states that "Provi information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulato status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".
- Justify the use of 4ml printed glass vial for packaging of drug product with reference to the volume of diluent used f reconstitution of dry powder for injection as per innovator product.
- Justify how you have performed pharmaceutical equivalence studies using the reference product of different strengt
- Submit data in section 3.2.P.2.3 (Manufacturing process development) as per the decision of 293rd meeting Registration Board, which states that "The selection and optimization of the manufacturing process described 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development sha be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of asept processing or other sterilization methods over terminal sterilization shall be provided".
- Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Boar which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should performed as per the instructions provided in individual label of the drug product*"
- Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, whi manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen fr water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodiu hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection evident from the detail manufacturing procedure given in section 3.2. P.3.3.
- Justify the weight variation limit of filled vial from1107-1152mg with reference to the claimed potency of both active
- Provide the Pharmacopeial reference of finished product specifications, since USP specs are mentioned in module and USP does not contain any monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection. Howeve monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection is present in Japanese Pharmacopeia.
- Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.
- According to the document submitted in section 3.2.P.8 batch no. T-CSP-002 and T-CSP-003 has been manufactur on 02-2021, while stability study data sheet submitted in section 3.2.P.8.3 stated these batches were manufactured sep-2021. Clarification required in this regard.
- Specify the batch size of all three stability batches.
- Justify the pH acceptance criteria (6.0-8.0) and water content acceptance limit (8.0-11%) set for drug product with t acceptance criteria mentioned on COA of drug substance by drug substance manufacturer i.e. 4.5-6.5 and NMT 3.0 Elevation of pH and water content of drug product without any further processing of formulation needs to be justi with the pharmacopeial reference and innovator product.

- Assay content of both active should be separately calculated and mentioned as per pharmacopeial reference an innovator product.
- As per release specification of drug product acceptance criteria of assay is 90-110% while the stability data she represents that assay content should be between 90-115%. Justification is required regarding the variation in acceptanc limit of assay content in various section of module-III.
- Justify why the sterility test is not included in the stability studies of the product.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug produc Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of the batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical repo / COA, raw data sheet and respective chromatograms separately for each time point.
- Provide Reference of previous approval of applications with stability study data of the firm (if any)
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time an accelerated).

In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.

Remarks of the Evaluator:

In response of above shortcomings, firm has submitted a complete new CTD dossier with fee of Rs.7500/- in which dru substance was imported from a new source and accordingly data of trial batches of drug product manufactured from ne source of drug substance has submitted. Newly submitted dossier has again evaluated and presented before the Board f its consideration.

	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22143 dated 11/04/2022
	Details of fee submitted	PKR 7,500/-: dated 02/08/2022
	The proposed proprietary name / brand name	Cef-Sulb Injection IV/IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder Cefoperazone sodium JP equivalent to Cefoperazone…….500mg Sterile Powder Sulbactam sodium JP equivalent to Sulbactam…….500mg
	Pharmaceutical form of applied drug	Dry powder for injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	JP Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 1gm by M/s Pfizer Ltd. USA, USFDA Approved.

	For generic drugs (me-too status)	Toxirid Injection 1gm by Global Pharmaceuticals, Reg. No. 042552
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co. Ltd. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefoperazone sodium /sulbactam sodium Injection is present in JP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (2003FJ81NH, 2002FJ81NH, 2001FJ81NH)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product 2SUM (Cefoperazone Sodium + Sulbactam Sodium) 1g Injection of M/s. Healthtek Pvt. Ltd. Karachi, performing quality tests (Identification, Assay, constituted solution, BET & sterility test).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Qilu Antibiotic Pharmaceutical Co. Ltd. China
API Lot No.	2001FJ81NH
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRI003-01	TRI003-02	TRI003-03
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	26-01-2022	26-01-2022	26-01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Qilu Antibiotics Pharmaceuticals Co. Ltd., China vide Dy. No. 11160/2021 DRAP Dated: 27-12-2021. Invoice attested vide Dy.no. 11160/2021 DRAP dated: 27-12-2021in which shipper was M/s. Shandong Luoxin Pharmaceuticals, China.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Shortcomings/Observations
1.	3.2. S.4.1	Acceptance criteria of assay mentioned in specification of drug was not in accordance with JP monograph. Assay limit mentioned in COA and specification of drug substance by both drug substance manufacturer and drug product manufacturer was Cefoperazone on anhydrous basis ≥43.5% and sulbactam on anhydrous basis ≥44.5%. / Assay acceptance criteria in accordance with JP monograph is "It contains not less than 90.0% and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24)".
2.	3.2. S.4.3	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2. S.5	Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
4.	3.2. S.7	Firm has submitted only 6 months long term stability data of all three batches of drug substance.
5.	3.2P.2.1(a)(b)	Firm has not provided any details related to weight of powder filled per vial keeping in view the sodium content of both active substances.

<table>
<tr><td>6.</td><td>3.2.P.2.1(C)</td><td>Firm has not provided any details regarding the type of diluent, its composition, quantity or volume, specifications (as applicable) in which drug product has to be reconstitute before administration.</td></tr>
<tr><td>7.</td><td>3.2. P.2.2.1</td><td>Firm has submitted the pharmaceutical equivalence report in which the acceptance criteria of all the quality test was not in accordance with JP monograph:
<table>
<tr><td>Acceptance criteria in pharmaceutical equivalence report</td><td>Acceptance criteria in JP monograph</td></tr>
<tr><td>pH (6.0-8.8)</td><td>pH (4.5-6.5)</td></tr>
<tr><td>Assay (90%-110%)</td><td>Assay (It contains not less than 90.0 and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24).)</td></tr>
<tr><td>Bacterial Endotoxin Test (NMT 0.2 USP Endotoxin unit per mg)</td><td>Bacterial Endotoxin Test (Less than 0.060 EU/mg (potency).)</td></tr>
</table>
Further firm has not performed water content test and clarity and color of solution test which are also included in JP monograph.</td></tr>
<tr><td>8.</td><td>3.2. P.5.2</td><td>Firm has not submitted the analytical procedure used for testing of drug product.</td></tr>
<tr><td>9.</td><td>3.2.P.5.3</td><td>Analytical method verification report reflects that the assay has performed on UV method while the JP monograph recommends the HPLC method for assay of drug product.</td></tr>
<tr><td>10.</td><td>3.2.P.6</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug product.</td></tr>
<tr><td>11.</td><td>3.2.P.8</td><td>Firm has not submitted following documents to support the stability data of drug product:
Reference of previous approval of applications with stability study data of the firm (if any)
Documents for the procurement of API with approval from DRAP (in case of import).
Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.</td></tr>
<tr><td>12.</td><td></td><td>Firm has not submitted the copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.</td></tr>
</table>

Decision: Deferred for submission of following:

- **Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.**
- **Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.**
- **COA of primary / secondary reference standard including source and lot number used for testing of drug substance.**
- **Submit long term stability data of drug substance till the claimed shelf life.**

- **Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.**
- **Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.**
- **Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.**
- **Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.**
- **COA of primary / secondary reference standard including source and lot number used for testing of drug product.**
- **Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.**
- **Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.**
- **Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.**
- **Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

506.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Hea Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. dated 11/04/2022
	Details of fee submitted	PKR 30,000/-: dated 28/03/2022
	The proposed proprietary name / brand name	Cef-Slub Injection IV/IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefoperazone sodium MS equivalent Cefoperazone 1g Sterile Powder of Sulbactam sodium MS equivalent Sulbactam 1g
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 2gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 2gm by Global Pharmaceuticals, Reg. N 042555
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Summarized information related to nomenclatur structure, general properties, solubilities, physical forn manufacturers, description of manufacturing process ar controls, impurities, specifications, analytical procedur and its verification, batch analysis and justification specification, reference standard, container closure syste and stability studies of drug substance and drug product submitted.
	Module III (Drug Substance)	Official monograph of Cefoperazone sodium /Sulbacta sodium eq to Cefoperazone /Sulbactam is present n present in any pharmacopeia. The firm as submitted deta of nomenclature, structure, general properties, solubilitie physical form, manufacturers, description of manufacturir process and controls, tests for impurity D, G & relate substances (impurity A & unspecified), specification analytical procedures and its verification, batch analys and justification of specification, reference standar container closure system and stability studies of dru substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (T-CSP001, T-CSP002, T-CSP003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, descriptio of manufacturing process and controls, impuritie specifications, analytical procedure (including dissolutio testing at acidic and buffer medium) and its verificatio studies, batch analysis and justification of specificatio reference standard, container closure system and stabili studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established again the brand leader that is Toxirid Injection 2gm by Glob Pharmaceuticals Pakistan performing quality tes (Identification, Assay, Constituted Solution, Uniformity dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted includir linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China		
API Lot No.	CEFP17/023/06/21		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leafl in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-CSP001	T-CSP002	Batch No.
Batch Size (Scientifically rational batch size)	1000 Vials	1000 Vials	Batch Siz (Scientifically rational batc size)

Manufacturing Date	09-2021	09-2021	Manufacturin Date
Date of Initiation	28-09-2021	28-09-2021	Date Initiation
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20191025 issued by CFDA valid till 10/12/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Letter No. 11160/2021/DRAP Dated: 27-07-2021 B/L No. 176-6445-291 dated: 31-07-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Shortcomings communicated to the Firm:

- You have mentioned USP specification in section 1.5.6 in module 1, while the drug product monograph is not availab in USP, but present in JP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both USP and in-house standards for the drug substance, provi scientific justification in this regard.
- Justify, how you have claimed USP specification for drug substance cefoperazone sodium+Sulbactum30-May-2 sodium, when the monograph has not been present in USP.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies th "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substan /Active Pharmaceutical Ingredient by both Drug substance manufacturer."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states th "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performe by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall b submitted". Further justify how the analysis of drug substance was conducted without performing verification studi of the analytical method of drug substance.
- Stability study data of 3 batches of drug substances till the assigned shelf life needs to be submitted, since stability da of 3 months has submitted despite the batch had been manufactured in 2017.
- Submit data in section 3.2.P.1 (c) as per the decision of 293rd meeting of Registration Board, which states that "Provi information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulato status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".
- Justify the use of 4ml printed glass vial for packaging of drug product with reference to the volume of diluent used f reconstitution of dry powder for injection as per innovator product.
- Justify how you have performed pharmaceutical equivalence studies using the reference product of different strengt
- Submit data in section 3.2.P.2.3 (Manufacturing process development) as per the decision of 293rd meeting Registration Board, which states that "The selection and optimization of the manufacturing process described 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development sha be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of asept processing or other sterilization methods over terminal sterilization shall be provided".
- Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Boar which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should b performed as per the instructions provided in individual label of the drug product*"

- Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, whi
  manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen fr
  water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodiu
  hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection
  evident from the detail manufacturing procedure given in section 3.2. P.3.3.
- Justify the weight variation limit of filled vial from1107-1152mg with reference to the claimed potency of both active
- Provide the Pharmacopeial reference of finished product specifications, since USP specs are mentioned in module
  and USP does not contain any monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection. Howeve
  monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection is present in Japanese Pharmacopeia.
- Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.
- According to the document submitted in section 3.2.P.8 batch no. T-CSP-002 and T-CSP-003 has been manufactur
  on 02-2021, while stability study data sheet submitted in section 3.2.P.8.3 stated these batches were manufactured
  sep-2021. Clarification required in this regard.
- Specify the batch size of all three stability batches.
- Justify the pH acceptance criteria (6.0-8.0) and water content acceptance limit (8.0-11%) set for drug product with t
  acceptance criteria mentioned on COA of drug substance by drug substance manufacturer i.e. 4.5-6.5 and NMT 3.0%
  Elevation of pH and water content of drug product without any further processing of formulation needs to be justi
  with the pharmacopeial reference and innovator product.
- Assay content of both active should be separately calculated and mentioned as per pharmacopeial reference a
  innovator product.
- As per release specification of drug product acceptance criteria of assay is 90-110% while the stability data she
  represents that assay content should be between 90-115%. Justification is required regarding the variation in acceptan
  limit of assay content in various section of module-III.
- Justify why the sterility test is not included in the stability studies of the product.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug produc
  Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of the
  batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical repo
  / COA, raw data sheet and respective chromatograms separately for each time point.
- Provide Reference of previous approval of applications with stability study data of the firm (if any)
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time a
  accelerated).

In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.

Remarks of the Evaluator:

In response of above shortcomings, firm has submitted a complete new CTD dossier with fee of Rs.7500/- in which dru
substance was imported from a new source and accordingly data of trial batches of drug product manufactured from ne
source of drug substance has submitted. Newly submitted dossier has again evaluated and presented before the Board f
its consideration.

	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22144 dated 04/08/2022

	Details of fee submitted	PKR 7,500/-: dated 02/08/2022
	The proposed proprietary name / brand name	Cef-Slub Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefoperazone sodium JP equivalent to Cefoperazone 1g Sterile Powder of Sulbactam sodium JP equivalent to Sulbactam 1g
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	JP Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 2gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 2gm by Global Pharmaceuticals, Reg. No. 042555
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co. Ltd. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefoperazone sodium /sulbactam sodium Injection is present in JP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (2003FJ81NH, 2002FJ81NH, 2001FJ81NH)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product 2SUM (Cefoperazone Sodium + Sulbactam Sodium) 2g Injection of M/s.

		Healthtek Pvt. Ltd. Karachi, performing quality tests (Identification, Assay, constituted solution, BET & sterility test).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Qilu Antibiotic Pharmaceutical Co. Ltd. China		
API Lot No.	2001FJ81NH		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRI004-01	TRI004-02	TRI004-03
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	26-01-2022	26-01-2022	26-01-2022
No. of Batches	03		

Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission license to import from M/s. Qilu Antibiotics Pharmaceuticals Co. Ltd., China vide Dy. No. 11160/2021 DRAP Dated: 27-12-2021. Invoice attested vide Dy.no. 11160/2021 DRAP dated: 27-12-2021in which shipper was M/s. Shandong Luoxin Pharmaceuticals, China.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Shortcomings/Observations

<table>
<tr><td>1.</td><td>3.2. S.4.1</td><td>Acceptance criteria of assay mentioned in specification of drug was not in accordance with JP monograph.<table><tr><td>Assay limit mentioned in COA and specification of drug substance by both drug substance manufacturer and drug product manufacturer was Cefoperazone on anhydrous basis ≥43.5% and sulbactam on anhydrous basis ≥44.5%.</td><td>Assay acceptance criteria in accordance with JP monograph is “It contains not less than 90.0% and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24)”.</td></tr></table></td></tr>
<tr><td>2.</td><td>3.2. S.4.3</td><td>Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.</td></tr>
<tr><td>3.</td><td>3.2. S.5</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug substance.</td></tr>
<tr><td>4.</td><td>3.2. S.7</td><td>Firm has submitted only 6 months long term stability data of all three batches of drug substance.</td></tr>
<tr><td>5.</td><td>3.2P.2.1(a)(b)</td><td>Firm has not provided any details related to weight of powder filled per vial keeping in view the sodium content of both active substances.</td></tr>
<tr><td>6.</td><td>3.2.P.2.1(C)</td><td>Firm has not provided any details regarding the type of diluent, its composition, quantity or volume, specifications (as applicable) in which drug product has to be reconstitute before administration.</td></tr>
<tr><td>7.</td><td>3.2. P.2.2.1</td><td>Firm has submitted the pharmaceutical equivalence report in which the acceptance criteria of all the quality test was not in accordance with JP monograph:<table><tr><td>Acceptance criteria in pharmaceutical equivalence report</td><td>Acceptance criteria in JP monograph</td></tr><tr><td>pH (6.0-8.8)</td><td>pH (4.5-6.5)</td></tr><tr><td>Assay (90%-110%)</td><td>Assay (It contains not less than 90.0 and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24).)</td></tr><tr><td>Bacterial Endotoxin Test (NMT 0.2 USP Endotoxin unit per mg)</td><td>Bacterial Endotoxin Test (Less than 0.060 EU/mg (potency).)</td></tr></table>Further firm has not performed water content test and clarity and color of solution test which are also included in JP monograph.</td></tr>
<tr><td>8.</td><td>3.2. P.5.2</td><td>Firm has not submitted the analytical procedure used for testing of drug product.</td></tr>
<tr><td>9.</td><td>3.2.P.5.3</td><td>Analytical method verification report reflects that the assay has performed on UV method while the JP monograph recommends the HPLC method for assay of drug product.</td></tr>
<tr><td>10.</td><td>3.2.P.6</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug product.</td></tr>
<tr><td>11.</td><td>3.2.P.8</td><td>Firm has not submitted following documents to support the stability data of drug product:
Reference of previous approval of applications with stability study data of the firm (if any)
Documents for the procurement of API with approval from DRAP (in case of import).
Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.</td></tr>
</table>

		• Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin. • Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co.,Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.
12.		Firm has not submitted the copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Decision: Deferred for submission of following:

- **Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.**
- **Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.**
- **COA of primary / secondary reference standard including source and lot number used for testing of drug substance.**
- **Submit long term stability data of drug substance till the claimed shelf life.**
- **Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.**
- **Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.**
- **Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.**
- **Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.**
- **COA of primary / secondary reference standard including source and lot number used for testing of drug product.**
- **Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.**
- **Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.**
- **Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.**
- **Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

507.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Dist Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.11609 dated 13/05/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021

	The proposed proprietary name / brand name	Citi-Pime Injection 1gm
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefepime HCL with L- Arginine Eq. Cefepime 1g
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime Injection 1g by M/s Hospira Inc. USA, USFDA Approved.
	For generic drugs (me-too status)	Zepime Injection 1g by Global Pharmaceuticals, Reg. N 046016
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Ltd India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Summarized information related to nomenclatur structure, general properties, solubilities, physical forn manufacturers, description of manufacturing process ar controls, impurities, specifications, analytical procedur and its verification, batch analysis and justification specification, reference standard, container closure syste and stability studies of drug substance and drug product submitted.
	Module III (Drug Substance)	Official monograph of Cefepime HCL with L- Arginine present in USP. The firm has submitted detail nomenclature, structure, general properties, solubilitie physical form, manufacturers, description of manufacturir process and controls, tests for impurity D, G & relate substances (impurity A & unspecified), specification analytical procedures and its verification, batch analys and justification of specification, reference standar container closure system and stability studies of dru substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CEIV/B1203011, CEIV/B120301 CEIV/B1203013)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, descriptio of manufacturing process and controls, impuritie specifications, analytical procedure (including dissolutio testing at acidic and buffer medium) and its verificatio studies, batch analysis and justification of specificatio reference standard, container closure system and stabili studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established again the comparator brand that is Zepime Injection 1g by Glob Pharmaceuticals Pakistan performing quality tes (Identification, Assay, Constituted Solution, Uniformity dosage form).

	Analytical method validation/verification of product	Method verification studies have submitted includin linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API		M/s Kopran Research Laboratories Ltd India	
API Lot No.		CFM-2104004	
Description of Pack (Container closure system)		One clear glass vial 15ml with LDPE ampoule of WFI or 1% Lidocain along with leaflet in unit carton.	
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		TC006-001	TC006-002 TC006-003
Batch Size (Scientifically rational batch size)		Not mentioned	Not mentioned Not mentione
Manufacturing Date		09-2021	09-2021 09-2021
Date of Initiation		02-2023	02-2023 02-2023
No. of Batches		03	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from MA Kopran Research laboratories,India vide Dy. No. 617 Dated: 16-04-2021. Invoice attested vide Dy.no. 6017/2021 DRAP dated: 2 04-2021in which exporter was M/s. Kopran Researc laboratories, India	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	

Remarks OF Evaluator:

Sr.no.	Section	Observations/Shortcomings	Reply of the Firm
1.	3.2.S.4.1 3.2. S.4.2	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm has not submitted the specifications and analytical procedure of drug substance by drug product manufacturer.
2.	3.2. S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.

		specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"	
3.	3.2. S.7	Submit complete long-term stability data of all three batches of drug substance, since only the complete data of batch no. CEIV/B1203011 has been submitted in section 3.2. S.7.	Firm has not submitted the long-term stability data of batch no. CEIV/B1203013.
4.	3.2. P.2.6	Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"	Firm has not submitted the reply in response of this query.
5.	3.2. P.3.1	Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.	Firm has submitted the amended document in which cefepime HCl with L-arginine is mentioned as the only active ingredient. However, the information regarding the quantity of dry powder filled per vial has not been given. Further, the flow chart of manufacturing process submitted in the reply of section 3.2.P.3.3 is of ceftriaxone.
6.	3.2.P.5.2	Provide complete analytical procedure used for routine testing of drug product since submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.	Firm again submit the copy of monograph of USP in section 3.2.P.5.2 and in section 3.2.P.4.2 submit the analytical procedure of cefotaxime injection.
7.	3.2.P.5.3	Analytical method of drug product verified in section	Firm has not given the reply in response of this query.

		3.2.P.5.3 is different from that specified in USP monograph. Justify, for using different analytical method for verification studies.	
8.	3.2.P.5.4	Scientific justification for not performing test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test during the batch release of the drug product	firm has submitted batch analysis report of three trail batches TRA-001, TRA-002, TRA-003 which were not the batch numbers of trial batches used for stability studies as evident from the submitted stability data sheets. Further, the test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test was not been included in batch analysis report nor given any justification. Furthermore, the firm submitted the same batch analysis report for cefepime 500mg injection and cefepime 1gm injection.
9.	3.2.P.6	Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.	Firm has submitted the reply in response of this query.
10.	3.2.P.8	Submit the stability data sheet of cefepime injection, since the submitted sheets are of ceftriaxone.	Firm stated that rectified and corrected stability data sheets are submitted.
11.	3.2.P.8	According to the document submitted in section 3.2. P.8 batch no. Cef-P-004, Cef-P-005and Cef-P-006 has been manufactured on 09-2021, while the dossier submitted in R&I of DRAP on 13th May,2022i.e. after 8 months of manufacturing of trial batches, clarification is required how you have submitted the stability data of real time study till 24month.	Firm stated that rectified and corrected stability data sheets are submitted. However, the firm submitted the raw data sheets of batch no. TC006-01, TC006-02, TC006-03.
12.		1. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. 2. Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Firm has only submitted the chromatograms and 21 CFR audit trail report of instant product. Remaining documents has not been provided by the firm.

		3. Provide Reference of previous approval of applications with stability study data of the firm (if any) 4. Documents for the procurement of API with approval from DRAP (in case of import). 5. Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. 6. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). 7. In-use stability studies of reconstituted injection is required along with proposed in-use storage statement and in-use shelf-life. 8. Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	

Decision: Deferred for submission of following:

- **Specifications as well as analytical method of the drug substance from the drug product manufacturer section 3.2.S.4.1 and 3.2. S.4.2.**
- **Analytical method verification report of drug substance performed by drug product manufacturer.**
- **Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-te period.**
- **Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.**
- **Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.**
- **Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.**
- **Analytical method verification report of assay testing of drug product,in compliance of USP monograph Cefepime Injection.**
- **Clarification regarding the trial batches which were actually manufactured for the stability study of applie product.**
- **Batch analysis report of all three trial batches, in which all the quality test should be included that a specify in USP monograph of Cefepime injection.**
- **Provide details that which lot number of drug substance has been used in manufacturing of each batch drug product. Also provide documents confirming evidence of import of each lot of drug substance used manufacturing of these batches of drug product.**
- **Provide data of stability batches properly arranged and supported by respective documents includi analytical report / COA, raw data sheet and respective chromatograms separately for each time point.**
- **Documents for the procurement of API with approval from DRAP (in case of import).**
- **Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stabili studies data is provided in Module 3 section 3.2. P.8.3.**

508.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited

		Factory: 3 K.M, Head Balloki Road, Phool Nagar, Dis Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11608 dated 13/05/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Citi-Pime Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefepime HCL with L-Arginine Eq. Cefepime 500mg
	Pharmaceutical form of applied drug	Dry powder for injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime Injection 500mg by M/s Hospira Inc. USA, USFDA Approved.
	For generic drugs (me-too status)	Zepime Injection 500mg by Global Pharmaceuticals, Re No. 046015
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Ltd,Maharashtra, Indi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Summarized information related to nomenclatur structure, general properties, solubilities, physical forn manufacturers, description of manufacturing process ar controls, impurities, specifications, analytical procedur and its verification, batch analysis and justification specification, reference standard, container closure syste and stability studies of drug substance and drug product submitted.
	Module III (Drug Substance)	Official monograph of Cefepime for injection is present USP. The firm has submitted detail of nomenclatur structure, general properties, solubilities, physical forn manufacturers, description of manufacturing process ar controls, tests for impurity D, G & related substanc (impurity A & unspecified), specifications, analytic procedures and its verification, batch analysis ar justification of specification, reference standard, contain closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

		Batches: (CEIV/B1203011, CEIV/B120301 CEIV/B1203013)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, descriptio of manufacturing process and controls, impuritie specifications, analytical procedure (including dissolutio testing at acidic and buffer medium) and its verificatio studies, batch analysis and justification of specificatio reference standard, container closure system and stabili studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established again the brand leader that is Zepime Injection 500mg by Glob Pharmaceuticals Pakistan performing quality tes (Identification, Assay, Constituted Solution, Uniformity dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted includir linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Kopran Research Laboratories Ltd India		
API Lot No.	CFM-2104004		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI or 1% Lidocair along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TC007-001	TC007-002	TC007-001
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentione
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2023	09-2023	09-2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6: Letter No. 6176/2021 DRAP dated: 22-04-2021 Invoice: bearing two different dy.no. and date 6017/2021 DRAP (22-04-2021) & 6176 (16-04-2021)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Observations/Shortcomings	Reply of the Firm
1.	3.2.S.4.1 3.2. S.4.2	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm has not submitted the specifications and analytical procedure of drug substance by drug product manufacturer.
2.	3.2. S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2. S.7	Submit complete long-term stability data of all three batches of drug substance, since only the complete data of batch no. CEIV/B1203011 has been submitted in section 3.2. S.7.	Firm has not submitted the long-term stability data of batch no. CEIV/B1203013.
4.	3.2. P.2.6	Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"	Firm has not submitted the reply in response of this query.
5.	3.2. P.3.1	Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is	Firm has submitted the amended document in which cefepime HCl with L-arginine is mentioned as the only active ingredient. However, the information regarding the quantity of dry powder filled per vial has not been given. Further, the flow chart of manufacturing process submitted in the reply of section 3.2.P.3.3 is of ceftriaxone.

		required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.	
6.	3.2.P.5.2	Provide complete analytical procedure used for routine testing of drug product since submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.	Firm again submit the copy of monograph of USP in section 3.2.P.5.2 and in section 3.2.P.4.2 submit the analytical procedure of cefotaxime injection.
7.	3.2.P.5.3	Analytical method of drug product verified in section 3.2.P.5.3 is different from that specified in USP monograph. Justify, for using different analytical method for verification studies.	Firm has not given the reply in response of this query.
8.	3.2.P.5.4	Scientific justification for not performing test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test during the batch release of the drug product	firm has submitted batch analysis report of three trail batches TRA-001, TRA-002, TRA-003 which were not the batch numbers of trial batches used for stability studies as evident from the submitted correct stability data sheets. Further, the test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test was not been included in batch analysis report nor given any justification. Furthermore, the firm submitted the same batch analysis report for cefepime 500mg injection and cefepime 1gm injection.
9.	3.2.P.6	Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.	Firm has not submitted the reply in response of this query.
10.	3.2.P.8	Submit the stability data sheet of cefepime injection, since the submitted sheets are of ceftriaxone.	Firm submitted the rectified and corrected stability data sheets.
11.	3.2.P.8	According to the document submitted in section 3.2. P.8 batch no. Cef-P-004, Cef-P-005and Cef-P-006 has been manufactured on 09-2021, while the dossier submitted in R&I of DRAP on 13th May,2022i.e. after 8 months of manufacturing of trial batches, clarification is required how you have submitted the stability data of real time study till 24month.	Firm stated that rectified and corrected stability data sheets are submitted and the corrected stability trial batches were of batch no. TC007-01, TC007-02, TC007-03.
12.		1. Provide details that which lot number of drug substance has been used in manufacturing of each	Firm has only submitted the chromatograms and 21 CFR audit trail report of instant product. Remaining documents has not been provided by the firm.

		batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. 2. Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. 3. Provide Reference of previous approval of applications with stability study data of the firm (if any) 4. Documents for the procurement of API with approval from DRAP (in case of import). 5. Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. 6. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). 7. In-use stability studies of reconstituted injection is required along with proposed in-use storage statement and in-use shelf-life. 8. Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	

Decision: Deferred for submission of following:

- **Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.**
- **Analytical method verification report of drug substance performed by drug product manufacturer.**
- **Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re test period.**
- **Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.**
- **Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.**
- **Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.**
- **Analytical method verification report of assay testing of drug product,in compliance of USP monograph of Cefepime Injection.**

- **Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.**
- **Batch analysis report of all three trial batches, in which all the quality test should be included that are specify in USP monograph of Cefepime injection.**
- **Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.**
- **Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point**
- **Documents for the procurement of API with approval from DRAP (in case of import).**
- **Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.**

509.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Dist Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10867 dated 29/04/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Cefask Capsule 200mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime as Trihydrate 200mg
	Pharmaceutical form of applied drug	Oral Capsule
	Pharmacotherapeutic Group of (API)	Third generation cephalosporin antibiotic
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	2x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 200 mg CAPSULE by SANOFI Aventis Spain Approved
	For generic drugs (me-too status)	Cefiget 200 mg Capsule by M/s GETZ Pharma
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Dist Kasur
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Summarized information related to nomenclatur structure, general properties, solubilities, physical form manufacturers, description of manufacturing process an controls, impurities, specifications, analytical procedur and its verification, batch analysis and justification specification, reference standard, container closure syste

		and stability studies of drug substance and drug product submitted.
	Module III (Drug Substance)	Official monograph of cefixime drug substance is prese in USP. The firm has submitted detail of nomenclatur structure, general properties, solubilities, physical form manufacturers, description of manufacturing process ar controls, tests for impurity D, G & related substanc (impurity A & unspecified), specifications, analytic procedures and its verification, batch analysis ar justification of specification, reference standard, contain closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36th month Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CFM1602001, CFM1602002, CFM1602003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, descriptio of manufacturing process and controls, impuritie specifications, analytical procedure (including dissolutio testing at acidic and buffer medium) and its verificatio studies, batch analysis and justification of specificatio reference standard, container closure system and stabili studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established agains the comparator brand Product: Maxophine 200mg Capsul Manufacturer: Global Pharmaceutical (Pvt.) Ltd. Batch no: 20H097 Mfg Date: 08-2020
	Analytical method validation/verification of product	Method verification studies have submitted includin linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur		
API Lot No.	Not mentioned		
Description of Pack (Container closure system)	Hard gelatin shell capsule, blistered in alu-pvc packed in standard un carton in 2x5s provided with leafinsert inside.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRA-001	TRA-002	TRA-003
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentione
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-2023	08-2023	08-2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.

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

Remarks OF Evaluator:

Sr.no.	Section	Observations/Shortcomings	Reply of the Firm
1.	1.5.7	• In section 1.5.7, you have claimed USP specification for drug product while in section 3.2.P.5.2 JP monograph for cefixime capsule has been attached which revealed that product is comply with JP specification. Clarify, how 200mg potency capsule comply dissolution acceptance criteria of JP monograph, since it is applicable for 50mg and 100mg. • Revised the specification of drug product along with requisite fee as per the monograph of cefixime capsule approved by DRAP dated 22nd March,2022 copy of monograph available on DRAP official website.	Firm replied that We have to revised the specification of drug product as approved by DRAP, but firm has not submitted the fee for change of specification.
2.	3.2.S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted."	Firm submitted the reply in which it is stated that "As mentioned in section 4.2 the analytical methods applied in course of release testing of Cefixime are based on the monograph of Cefixime of USP 42. These methods are followed without any deviation".
3.	3.2. S.4.4	Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product	Firm submitted the COA of three batches of API.

		development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of different batches than that used in the manufacturing of stability batches.	
4.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2. S.5.	Firm has submitted the requisite information.
5.	3.2.S.7	The manufacturing date of API batches was feb,2016 while the approval of cefixime API was granted on 24th July, 2018 by DRAP as evident from the submitted approval letter. Clarify the manufacturing of cefixime API prior grant of approval from DRAP.	In the reply Firm submitted the stability data of different batches of drug substance which were manufactured in October,2018 and having batch no. (CFM1602001, CFM1602002, CFM1602003)
6.	3.2.P.2.2.1	Conclusion of comparative dissolution profile of cefixime capsule specified the f2 values of paracetamol and caffeine, clarification is required in this regard.	Firm in their reply stated that "it was typographic error and rectified," but not submitted the correct CDP report.
7.	3.2.P.5.1	• Scientific justification is required for using different assay method from that specified in JP monograph with reference to the chromatographic condition and preparation of standard and sample solutions. • According to JP monograph the assay limit should be not less than 90.0% and not more than 105.0% of the labelled potency of cefixime, justify, for keeping the wider acceptance criteria for assay of drug product than JP specifications i.e. 90% to 110%.	Firm replied that they have now switches over to the monograph of cefixime capsule approved by DRAP. However, the specifications of drug product given in the reply was not comply with the said monograph of cefixime capsule
8.	3.2.P.5.2	Firm again submitted the copy of monograph of JP instead of submitting the analytical procedure in accordance with DRAP approved monograph of cefixime capsule.	
9.	3.2.P.5.3	Analytical method validation report submitted in the reply was also not complying the claim pharmacopeial reference of drug product i.e. DRAP's approved monograph of cefixime capsule.	
10.	3.2.P.5.4	Firm submitted the batch analysis report which evident that the specifications of quality test were not in accordance claimed pharmacopeial. Further the results of dissolution test were also included in batch analysis report.	
11.	3.2.P.8	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance	Firm has not submitted the requisite information.

		used in manufacturing of these batches of drug product.	
12.	3.2P.8	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Firm submitted the supportive documents of different stability batches of drug product. Stability summary data sheets were of batch no. (TRA-001,TRA-002,TRA-003),while supportive documents (chromatogram, raw data sheets& COA) were of TRC-001,TRC-002,TRC-003.
13.	3.2.p.8	• Documents for the procurement of API with approval from DRAP (in case of import). • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted these documents.

Decision: Deferred for submission of following:

- **Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**
- **Analytical method verification report of drug substance performed by drug product manufacturer.**
- **Revised CDP report of drug product, performed against the innovator product.**
- **Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2 according the monograph approved by DRAP.**
- **Analytical method validation report of assay testing of drug product.**
- **Batch analysis report of all three trial batches of drug, in which all the quality test should be included that a the part of approved monograph of cefixime capsule.**
- **Clarification regarding the trial batches which were actually manufactured for the stability study of applie product and provide the supporting document of same batches.**
- **Details that which lot number of drug substance has been used in manufacturing of each batch of drug produc Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing these batches of drug product.**
- **Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies da is provided in Module 3 section 3.2. P.8.3.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority country of origin.**

510.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Dis Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 10336 dated 22/04/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Cefask DS Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml reconstituted suspension contains: Cefixime as Trihydrate 200mg
	Pharmaceutical form of applied drug	Oral suspension
	Pharmacotherapeutic Group of (API)	Third generation cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1X30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX Suspension USFDA Approved
	For generic drugs (me-too status)	Cefiget 200 mg/5ml Suspension by M/s GETZ Pharma
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Dis Kasur
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Summarized information related to nomenclatur structure, general properties, solubilities, physical forn manufacturers, description of manufacturing process ar controls, impurities, specifications, analytical procedur and its verification, batch analysis and justification specification, reference standard, container closure syste and stability studies of drug substance and drug product submitted.
	Module III (Drug Substance)	Official monograph of cefixime drug substance is prese in USP. The firm has submitted detail of nomenclatur structure, general properties, solubilities, physical forn manufacturers, description of manufacturing process ar controls, tests for impurity D, G & related substanc (impurity A & unspecified), specifications, analytic procedures and its verification, batch analysis ar justification of specification, reference standard, contain closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36th month Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CFM1602001, CFM1602002, CFM1602003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, descriptio of manufacturing process and controls, impuritie specifications, analytical procedure (including dissolutio testing at acidic and buffer medium) and its verificatio studies, batch analysis and justification of specificatio reference standard, container closure system and stabili studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established again the comparator brand REFFERENCE PRODUCT CEFIGET DS SUSPENSION Manufacturer: GETZ Pharma Batch NO.: 865 MFG Date: 11-2020

	Analytical method validation/verification of product	Method verification studies have submitted includir linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur		
API Lot No.	Not mentioned		
Description of Pack (Container closure system)	1 x 30ml (after reconstitution) Filled in amber glass bottle; labelled ar packed in standard unit carton provided with leaflet inside.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRS-004	TRS-005	TRS-006
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentione
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-2023	08-2023	08-2023
No. of Batches	03		

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

Remarks OF Evaluator:

Sr.no.	Section	Observations/Shortcomings	Reply of the Firm
1.	3.2.S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted."	Firm submitted the reply in which it is stated that "As mentioned in section 1.4.2 the analytical methods applied in course of release testing of Cefixime are based on the monograph of Cefixime of USP 42. These methods are followed without any deviation".

2.	3.2. S.4.4	Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of different batches than that used in the manufacturing of stability batches.	Firm submitted the COA of three batches of API.
3.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2. S.5.	Firm has submitted the requisite information.
4.	3.2.S.7	The manufacturing date of API batches was feb,2016 while the approval of cefixime API was granted on 24th July, 2018 by DRAP as evident from the submitted approval letter. Clarify the manufacturing of cefixime API prior grant of approval from DRAP.	In the reply Firm submitted the stability data of different batches of drug substance which were manufactured in October,2018 and having batch no. (CFM1602001, CFM1602002, CFM1602003)
5.	3.2. P.3.1	The bottle fill weight mentioned in section 3.2.P.3.1 is 1266mg while the objective weight per bottle mentioned in process validation report is 6.56mg. Justification is required in this regard.	Firm clarified that 1266mg of suspension powder filled per bottle.
6.	3.2. P.5.1	Justify why weight variation test, test of uniformity of dosage unit and deliverable volume were not included in the specification of drug product.	Firm submitted the specification of drug product in which again not including the weight variation test, test of uniformity of dosage unit and deliverable volume test neither submitted justification.
7.	3.2. P.5.2	Provide complete analytical procedure used for routine testing of drug product, submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.	Firm has submitted the copy of USP monograph of cefixime drug substance in section 3.2.P.5.2 instead detailed analytical procedure of cefixime suspension in compliance of USP monograph of cefixime for oral suspension.
8.	3.2. P.5.3	Following observations have been found in the analytical method verification report, clarification is required in this regard: 1. Assay method which has been verified is not in line with USP monograph, justify how the drug product comply with USP specification. 2. How the verification report of cefixime capsule be applied on cefixime suspension, since the	Firm did not submit any reply in response of this query.

		submitted analytical method verification report is of cefixime capsule.	
9.	3.2.P.5.4	Batch analysis report in section 3.2. P.5.4. reflect that filled weight was 65.6 mg ±5% while the COA of drug product on page 263 specified that average weight should be 17.5g±2.5%, justification is required in this regard.	Firm submitted the batch analysis report of three trail batches in which the weight of filled powder varied between 211mg to 213mg, while the average filled weight of powder per bottle in accordance with data given in section 3.2.P.3.1.should be 1266mg.
10.	3.2.P.8	• Clarification is required either the dissolution testing is included in the specification of drug product, since the result of dissolution testing was included in the stability data sheets of all three trial batches. • Justify for changing the assay limits in the long-term stability data of drug product.	Firm has not submitted any clarification/justification regarding these queries and submitted the new stability data sheet along with supportive documents of trail batches (TRS-004, TRS-005, TRS-006).
11.	3.2.P.8	• Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. • Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm submitted the requisite documents.
12.	3.2.P.8	• Documents for the procurement of API with approval from DRAP (in case of import). • Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted these documents.

Decision: Deferred for submission of following:

- **Fee of Rs. 7,500 for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**
- **Analytical method verification report of drug substance performed by drug product manufacturer.**
- **Revised CDP report of drug product, performed against the innovator product.**
- **Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2 according the USP monograph.**
- **Analytical method verification report of assay testing of drug product according to the USP monograph cefixime suspension.**
- **Clarification regarding the disparity observed in the bottle fill weight both in section 3.2. P.3.1. and 3.2. P.5.4.**

• **Clarification regarding the trial batches which were actually manufactured for the stability study of applic product and provide the supporting document of same trial batches.** • **Details that which lot number of drug substance has been used in manufacturing of each batch of drug produc Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing these batches of drug product.** • **Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies da is provided in Module 3 section 3.2. P.8.3.** **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority country of origin.**		
511.	Name, address of Applicant / Marketing Authorization Holder	Variant Pharmaceuticals (Pvt.) Ltd
	Name, address of Manufacturing site.	Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqpur Roa District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No.4542 dated 17/02/2022
	Details of fee submitted	PKR 30,000/- dated 01/02/2022
	The proposed proprietary name / brand name	VILDAMET 50/500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains Metformin HCl …..500mg Vildagliptin ……..50mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Biguanide/Dipeptidyl peptidase-4 inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vildagliptin/Metformin 50mg/850mg film coated tabl by Teva Nederland BV, Swensweg 5, Haarlem, 2031GA Netherlands. MHRA Approved.
	For generic drugs (me-too status)	Galvus Met 50/500 mg TABLET by M/s Novart Pharmaceuticals Ltd., Reg. No. 066107
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020 General Tablet, General Capsule, General Sachet an General dry powder injectable (pre-lyophilized)
	Name and address of API manufacturer.	METFORMIN AARTI DRUGS LIMITED. Plot No. 211-213, Road No. 2 G.I.D.C., Sarigam, Dist.: Valsad-396 155 Gujarat. INDIA. VILDAGLIPTIN Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Summarized information related to nomenclatur

		structure, general properties, solubilities, physical form manufacturers, description of manufacturing process an controls, impurities, specifications, analytical procedure and its verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance and dru product is submitted.
	Module III (Drug Substance)	Official monograph of Metformin HCl and Vildagliptin present in both USP/BP. The firm as submitted detail nomenclature, structure, general properties, solubilitie physical form, manufacturers, description manufacturing process and controls, tests for impurity related substances, specifications, analytical procedure and its verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: METFORMIN (MEF/1410027, MEF/1410028, MEF/1410029) Vildagliptin 20160927,20161031,20161123
	Module-III (Drug Product):	The firm has submitted detail of manufacturer description of manufacturing process and control impurities, specifications, analytical procedure (includin dissolution testing at acidic and buffer medium) and i verification studies, batch analysis and justification specification, reference standard, container closu system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been establishe against the innovator brand that is Galvus Met 50/500 m Tablet by M/s Novartis Pharmaceuticals Ltd., Reg. N 066107 by performing quality tests includ (Identification, Assay, Dissolution,). CDP has been performed against the same brand that Galvus Met 50/500 mg Tablet by M/s Novart Pharmaceuticals Ltd., in Acid media (pH 1.2), Aceta buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The valu for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted includin linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	METFORMIN HCL AARTI DRUGS LIMITED. Plot No. 211-213, Road No. 2 G.I.D.C., Sarigam, Dist.: Valsad-396 15 Gujarat. INDIA VILDAGLIPTIN Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
API Lot No.	MEF/11010279 (METFORMIN) WT-20200314-D01-WT03-02 (VILDAGLIPTIN)
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	16-06-2021	18-06-2021	19-06-2021
Date of Initiation	19-06-2021	22-06-2021	22-06-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	METFORMIN Copy of GMP certificate No. 20031933 FDA INDIA issued by FDA INDIA valid till 19-03-2023. VILDAGLIPTIN Copy of GMP certificate issued by Fuxin FDA China valid till 27-09-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.4111/2020/DRAP-AD-CD(I&E) dated 18/03/2020 is submitted wherein the permissio to import different APIs including METFORMIN HC for the purpose of test/analysis and stability studies is granted. • Invoice # EXP/1023/20-21 AD date 23-07-2020 • Invoice # HN200812-Q AD date 09-10-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Reply of the firm
1.	3.2. S.4	Provide detailed analytical procedures for the testing of drug substance by drug product manufacturer. Provide analytical Method validation studies performed by the Drug Product manufacturer.	Firm has submitted analytical procedures used for testing of both drug substances along with analytical method verification reports.
2.	3.2. S.7	Provide complete stability data of drug substance till the claimed shelf life since the submitted data is of 24 months despite the study had performed in 2016.	Firm has submitted the complete stability of drug substance till claimed shelf life i.e.36months.

<table>
<tr><td>3.</td><td>3.2. P.1</td><td>Justify the choice of excipients in your formulation, since the excipients used are different from that of the innovator / reference product. Further justify how the formulation was developed without performing drug-excipient compatibility studies.</td><td>Firm has submitted the results of 6month real time stability data of drug product under the head of compatibility analysis sheet.</td></tr>
<tr><td>4.</td><td>3.2. P.2.2</td><td>Specify details including batch number and manufacturing date of the reference / comparator product against which pharmaceutical equivalence is performed.</td><td>Firm has submitted following details:
<table>
<tr><td>Brand name</td><td>Batch no.</td><td>Mfg Date</td><td>Exp Date</td><td>Manufacturer</td></tr>
<tr><td>Galvus Met (Reg.no.786106)</td><td>KAR88</td><td>12-2020</td><td>05-2022</td><td>Novartis Singapore</td></tr>
</table></td></tr>
<tr><td>5.</td><td>3.2.P.2.2</td><td>• Submit the data of comparative dissolution profile in comply with the decision of 293rd meeting of Registration Board.</td><td>Firm has submitted the complete data of comparative dissolution profile in accordance with the decision of 293rd meeting of Registration Board.</td></tr>
<tr><td>6.</td><td>3.2. P.5</td><td>Justify the adaptation of dissolution acceptance criteria as NLT 80% in 30 minutes since the review documents of MHRA approved innovator product specifies the dissolution criteria as 85% (Q) in 30 minutes for both drug substance. Dissolution data of stability study submitted in the relevant section i.e.3.2.P.8 supported the acceptance limit of innovator product.</td><td>Firm replied that they update the acceptance criteria to NLT 85%(Q) in 30 minutes.</td></tr>
<tr><td>7.</td><td colspan="2">Submit valid GMP certificate of the drug substance vildagliptin manufacturer since the submitted GMP certificate was valid till 29-07-2020.</td><td>Firm submit the valid GMP certificate of drug substance Vildagliptin which is valid till 23-08-2023.</td></tr>
</table>

Decision: Approved.

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

<table>
<tr><td rowspan="4">512.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>Variant Pharmaceuticals (Pvt.) Ltd</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqp Road District Sheikhupura.</td></tr>
<tr><td>Status of the applicant</td><td>☒ Manufacturer
☐ Importer
☐ Is involved in none of the above (contract giver</td></tr>
<tr><td>Status of application</td><td>☐ New Drug Product (NDP)</td></tr>
</table>

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No.4543 dated 17/02/2022
	Details of fee submitted	PKR 30,000/-: dated 01/02/2022
	The proposed proprietary name / brand name	Vildamet 50/850mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains Metformin HCl ….850mg Vildagliptin …….50mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Biguanide/Dipeptidyl peptidase-4 inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vildagliptin/Metformin 50mg/850mg film coate tablet by Teva Nederland BV, Swensweg Haarlem, 2031GA, Netherlands. MHRA Approve
	For generic drugs (me-too status)	Galvus Met 50/850 mg TABLET by M/s Novart Pharmaceuticals Ltd., Reg. No. 066106
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020 General Tablet, General Capsule, General Sach and General dry powder injectable (pre-lyophilize
	Name and address of API manufacturer.	METFORMIN AARTI DRUGS LIMITED. Plot No. 211-213, Road No. 2 G.I.D.C., Sarigam, Dist.: Valsad-396 155 Gujarat. INDIA. VILDAGLIPTIN Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general properties solubilities, physical form, manufacturer description of manufacturing process and control impurities, specifications, analytical procedures a its verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance a drug product is submitted.
	Module III (Drug Substance)	Official monograph of Metformin HCl a Vildagliptin is present in USP/BP. The firm submitted detail of nomenclature, structure, gener properties, solubilities, physical form manufacturers, description of manufacturing proce and controls, tests for impurity & related substance specifications, analytical procedures and verification, batch analysis and justification

		specification, reference standard, container closu system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 mont Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 mont Batches: Metformin (MEF/1410027, MEF/1410028, MEF/1410029) Vildagliptin 20160927,20161031,20161123
	Module-III (Drug Product):	The firm has submitted detail of manufacturer description of manufacturing process and control impurities, specifications, analytical procedu (including dissolution testing at acidic and buff medium) and its verification studies, batch analys and justification of specification, reference standar container closure system and stability studies of dru product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been establishe against the innovator brand that is Galvus M 50/850 mg Tablet by M/s Novartis Pharmaceutica Ltd., Reg. No. 066106 by performing quality tes (Identification, Assay, Dissolution,). CDP has been performed against the same brand th is Galvus Met 50/850 mg Tablet by M/s Novart Pharmaceuticals Ltd., in Acid media (pH 1.2 Acetate buffer (pH 4.5) & Phosphate Buffer (p 6.8). The values for f1 and f2 are in the acceptab range.
	Analytical method validation/verification of product	Method verification studies have submitte including linearity, range, accuracy, precisio specificity.

STABILITY STUDY DATA

Manufacturer of API	METFORMIN HCL AARTI DRUGS LIMITED. Plot No. 211-213, Road No. 2 G.I.D.C., Sarigam, Dist.: Valsad-396 15 Gujarat. INDIA VILDAGLIPTIN Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	MEF/11010279 (METFORMIN) WT-20200314-D01-WT03-02 (VILDAGLIPTIN)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	10-06-2021	12-06-2021	12-06-2021
Date of Initiation	14-06-2021	16-06-2021	16-06-2021

No. of Batches		03
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	METFORMIN Copy of GMP certificate No. 20031933 FDA INDIA issued by FDA INDIA valid till 19-03-202 VILDAGLIPTIN Copy of GMP certificate issued by Fuxin FDA China valid till 27-09-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.4111/2020/DRAP-AD-CD(I&E) dated 18/03/2020 is submitted wherei the permission to import different APIs includin METFORMIN HCl for the purpose of test/analysis and stability studies is granted. • Invoice # EXP/1023/20-21 AD date 23-07-2020 • Invoice # HN200812-Q AD date 09-10-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Reply of the firm
8.	3.2. S.4	Provide detailed analytical procedures for the testing of drug substance by drug product manufacturer. Provide analytical Method validation studies performed by the Drug Product manufacturer.	Firm has submitted analytical procedures used for testing of both drug substances along with analytical method verification reports.
9.	3.2. S.7	Provide complete stability data of drug substance till the claimed shelf life since the submitted data is of 24 months despite the study had performed in 2016.	Firm has submitted the complete stability of drug substance till claimed shelf life i.e.36months.
10.	3.2. P.1	Justify the choice of excipients in your formulation, since the excipients used are different from that of the innovator / reference product. Further justify how the formulation was developed without performing drug-excipient compatibility studies.	Firm has submitted the results of 6month real time stability data of drug product under the head of compatibility analysis sheet.

<table>
<tr><td>11.</td><td>3.2. P.2.2</td><td>Specify details including batch number and manufacturing date of the reference / comparator product against which pharmaceutical equivalence is performed.</td><td>Firm has submitted following details:<table><tr><td>Brand name</td><td>Batch no.</td><td>Mfg Date</td><td>Exp Date</td><td>Manufacturer</td></tr><tr><td>Galvus Met (Reg.no.066106)</td><td>KAR42</td><td>01-2021</td><td>06-2022</td><td>Novartis Singapore</td></tr></table></td></tr>
<tr><td>12.</td><td>3.2.P.2.2</td><td>• Submit the data of comparative dissolution profile in comply with the decision of 293rd meeting of Registration Board.</td><td>Firm has submitted the complete data of comparative dissolution profile in accordance with the decision of 293rd meeting of Registration Board.</td></tr>
<tr><td>13.</td><td>3.2. P.5</td><td>Justify the adaptation of dissolution acceptance criteria as NLT 80% in 30 minutes since the review documents of MHRA approved innovator product specifies the dissolution criteria as 85% (Q) in 30 minutes for both drug substance. Dissolution data of stability study submitted in the relevant section i.e.3.2.P.8 supported the acceptance limit of innovator product.</td><td>Firm replied that they update the acceptance criteria to NLT 85%(Q) in 30 minutes.</td></tr>
<tr><td>14.</td><td colspan="2">Submit valid GMP certificate of the drug substance vildagliptin manufacturer since the submitted GMP certificate was valid till 29-07-2020.</td><td>Firm submit the valid GMP certificate of drug substance Vildagliptin which is valid till 23-08-2023.</td></tr>
</table>

Decision: Approved.

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

513.	Name, address of Applicant / Marketing Authorization Holder	M/s. Variant Pharmaceuticals (Pvt.) Ltd.
	Name, address of Manufacturing site.	Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqp Road District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4544 dated 17/02/2022
	Details of fee submitted	PKR 30,000/-: dated 01/02/2022
	The proposed proprietary name / brand name	VILDAMET 50/1000mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains Metformin HCl ….1000mg Vildagliptin ……..50mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Biguanide/Dipeptidyl peptidase-4 inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vildagliptin/Metformin 50mg/1000mg film coate tablet by Teva Nederland BV, Swensweg Haarlem, 2031GA, Netherlands. MHRA Approve
	For generic drugs (me-too status)	Galvus Met 50/1000 mg TABLET by M/s Novart Pharmaceuticals Ltd., Reg. No. 066107
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020 General Tablet, General Capsule, General Sach and General dry powder injectable (pre-lyophilize
	Name and address of API manufacturer.	METFORMIN AARTI DRUGS LIMITED. Plot No. 211-213, Road No. 2 G.I.D.C., Sarigam, Dist.: Valsad-396 155 Gujarat. INDIA. VILDAGLIPTIN Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general propertie solubilities, physical form, manufacturer description of manufacturing process and control impurities, specifications, analytical procedures ar its verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance ar drug product is submitted.
	Module III (Drug Substance)	Official monograph of Metformin HCl ar Vildagliptin is present in USP/BP. The firm submitted detail of nomenclature, structure, gener properties, solubilities, physical form manufacturers, description of manufacturing proce and controls, tests for impurity & related substance specifications, analytical procedures and i verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 month Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 month Batches: METFORMIN (MEF/1410027, MEF/1410028, MEF/1410029) Vildagliptin 20160927,20161031,20161123

	Module-III (Drug Product):	The firm has submitted detail of manufacturer description of manufacturing process and control impurities, specifications, analytical procedu (including dissolution testing at acidic and buff medium) and its verification studies, batch analys and justification of specification, reference standar container closure system and stability studies of dru product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been establishe against the innovator brand that is Galvus M 50/1000 mg Tablet by M/s Novartis Pharmaceutica Ltd., Reg. No. 066106 by performing quality tes (Identification, Assay, Dissolution,). CDP has been performed against the same brand th is Galvus Met 50/1000 mg Tablet by M/s Novart Pharmaceuticals Ltd., in Acid media (pH 1.2 Acetate buffer (pH 4.5) & Phosphate Buffer (p 6.8). The values for f1 and f2 are in the acceptab range.
	Analytical method validation/verification of product	Method verification studies have submitte including linearity, range, accuracy, precisio specificity.

STABILITY STUDY DATA			
Manufacturer of API	METFORMIN HCL AARTI DRUGS LIMITED. Plot No. 211-213, Road No. 2 G.I.D.C., Sarigam, Dist.: Valsad-396 15 Gujarat. INDIA VILDAGLIPTIN Fuxin Long Rui Pharmaceutical Co. Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	MEF/11010279 (METFORMIN) WT-20200314-D01-WT03-02 (VILDAGLIPTIN)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	02-06-2021	05-06-2021	05-06-2021
Date of Initiation	05-06-2021	10-06-2021	10-06-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	METFORMIN Copy of GMP certificate No. 20031933 FDA INDIA issued by FDA INDIA valid till 19-03-202 VILDAGLIPTIN Copy of GMP certificate issued by Fuxin FDA China valid till 27-09-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.4111/2020/DRAP-AD-CD(I&E) dated 18/03/2020 is submitted wherei the permission to import different APIs includin METFORMIN HCl for the purpose of test/analysis and stability studies is granted. • Invoice # EXP/1023/20-21 AD date 23-07-2020 • Invoice # HN200812-Q AD date 09-10-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Reply of the firm
	3.2. S.4	Provide detailed analytical procedures for the testing of drug substance by drug product manufacturer. Provide analytical Method validation studies performed by the Drug Product manufacturer.	Firm has submitted analytical procedures used for testing of both drug substances along with analytical method verification reports.
2.	3.2. S.7	Provide complete stability data of drug substance till the claimed shelf life since the submitted data is of 24 months despite the study had performed in 2016.	Firm has submitted the complete stability of drug substance till claimed shelf life i.e.36months.
3.	3.2. P.1	Justify the choice of excipients in your formulation, since the excipients used are different from that of the innovator / reference product. Further justify how the formulation was developed without performing drug-excipient compatibility studies.	Firm has submitted the results of 6month real time stability data of drug product under the head of compatibility analysis sheet.
4.	3.2. P.2.2	Specify details including batch number and manufacturing date of the reference / comparator product against which	Firm has submitted following details:

Brand name	Batch no.	Mfg Date	Exp Date	Manufacturer
Galvus Met (Reg.no.066107)	KAR86	01-2021	06-2022	Novartis Singapore

		pharmaceutical equivalence is performed.	
5.	3.2. P.2.2	• Submit the data of comparative dissolution profile in comply with the decision of 293rd meeting of Registration Board.	Firm has submitted the complete data of comparative dissolution profile in accordance with the decision of 293rd meeting of Registration Board.
6.	3.2. P.5	Justify the adaptation of dissolution acceptance criteria as NLT 80% in 30 minutes since the review documents of MHRA approved innovator product specifies the dissolution criteria as 85% (Q) in 30 minutes for both drug substances. Dissolution data of stability study submitted in the relevant section i.e.3.2.P.8 supported the acceptance limit of innovator product.	Firm replied that they update the acceptance criteria to NLT 85%(Q) in 30 minutes.
7.	Submit valid GMP certificate of the drug substance vildagliptin manufacturer since the submitted GMP certificate was valid till 29-07-2020.		Firm submit the valid GMP certificate of drug substance Vildagliptin which is valid till 23-08-2023.

Decision: Approved.

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

514.	Name, address of Applicant / Marketing Authorization Holder	Variant Pharmaceuticals (Pvt.) Ltd
	Name, address of Manufacturing site.	Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqp Road District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8309 dated 30/03/2022
	Details of fee submitted	PKR 30,000/-: dated 09/03/2022
	The proposed proprietary name / brand name	AMLOSARTAN 5/80mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains Amlodipin Besylate eq. to Amlodipine …..5mg Valsartan…….80mg
	Pharmaceutical form of applied drug	Film Coated Tablet.

	Pharmacotherapeutic Group of (API)	Calcium channel blocker & Angiotensin II recept blockers
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Amlodipine/Valsartan Mylan 5 mg/80 mg filn coated tablets by Mylan Germany Gmb Zweigniederlassung Bad Homburg v. d. Hoel Benzstrasse 1, Bad Homburg v. d. Hoehe, Hesse 61352 Germany , MHRA Approved.
	For generic drugs (me-too status)	Exforge 5/80 mg tablets by by M/s Novart Pharmaceuticals Ltd, Reg. No. 047569
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020 General Tablet, General Capsule, General Sach and General dry powder injectable (pre-lyophilize
	Name and address of API manufacturer.	CADILA PHARMACEUTICALS LIMITED. (Amlodipine Besylate) 294, GIDC Industrial Estate, Ankleshwar-393 002 Gujarat. INDIA. Zhuhai Rundu Pharmaceutical Co., Ltd. (Valsartan No.6, North Airport Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province, 519041, P. R. of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general propertie solubilities, physical form, manufacturer description of manufacturing process and control impurities, specifications, analytical procedures ar its verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance ar drug product is submitted.
	Module III (Drug Substance)	Official monograph of Amlodipine Besylate ar Valsartan is present in USP/BP. The firm submitted detail of nomenclature, structure, gener properties, solubilities, physical form manufacturers, description of manufacturing proce and controls, tests for impurity & related substance specifications, analytical procedures and i verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 month Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 month
	Module-III (Drug Product):	The firm has submitted detail of manufacturer description of manufacturing process and control impurities, specifications, analytical procedu (including dissolution testing at acidic and buff medium) and its verification studies, batch analys and justification of specification, reference standar container closure system and stability studies of dru product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been establishe against the innovator brand that is Exforge 5/80m Tablet by M/s Novartis Pharmaceuticals Ltd, Re No. 047569 by performing quality tes (Identification, Assay, Dissolution,). CDP has been performed against the same brand th is Exforge 5/80mg Tablet by M/s Novartis, in Ac media (pH 1.2), Acetate buffer (pH 4.5) Phosphate Buffer (pH 6.8). The values for f1 and are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitte including linearity, range, accuracy, precisio specificity.

STABILITY STUDY DATA			
Manufacturer of API	CADILA PHARMACEUTICALS LIMITED. (Amlodipine Besylate) 294, GIDC Industrial Estate, Ankleshwar-393 002 Gujarat. INDIA. Zhuhai Rundu Pharmaceutical Co., Ltd. (Valsartan) No.6, North Airport Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province, 519041, P. R. of China		
API Lot No.	20AD096 (Amlodipine) 67820030604 (Valsartan)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	02-07-2021	10-07-2021	17-07-2021
Date of Initiation	09-07-2021	16-07-2021	22-07-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	AMLODIPINE BESLYLATE: Copy of GMP certificate No. 18101065 FDA INDIA issued by FDA INDIA valid till 18-10-202 VALSARTAN: Copy of GMP certificate No. GD20160649 FDA CHINA issued by FDA CHINA valid till 13-11-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.4111/2020/DRAP-AD-CD(I&E) dated 18/03/2020 is submitted wherei the permission to import different APIs includin AMLODIPINE BESYLATE & VALSARTAN for the purpose of test/analysis and stability studies is granted. • Invoice # CPL/BD/SAM/003/20-21 AD date 09 10-2020 FOR AMLODIPINE

		• Invoice # RD2020060101-1 AD date 23-07-202 FOR VALSARTAN
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	3.2. S.4	• Provide detailed analytical procedures for the testing of both drug substance by drug product manufacturer. • Provide analytical Method validation studies of drug substance amlodipine performed by the drug product manufacturer.	Firm has submitted analytical procedures used for testing of both drug substances along with analytical method verification reports.
2.	3.2. P.1	• Justify the choice of excipients in your formulation, since the excipients used are different from that of the innovator / reference product. Further justify how the formulation was developed without performing drug-excipient compatibility studies.	Firm has submitted the results of 6month real time stability data of drug product under the head of compatibility analysis sheet.
3.	3.2. P.2.2	Specify details including batch number and manufacturing date of the reference / comparator product against which pharmaceutical equivalence is performed.	Firm has submitted following details: Brand name: Exforge (Reg.no.047569); Batch no.: BYH80; Mfg Date: 12-2020; Exp Date: 11-2023; Manufacturer: Novartis Pakistan
4.	3.2.P.2.2	Justify, the below 80% (Q) release of valsartan of test product in pH 6.8 medium with reference to the acceptance criteria of USP monograph.	Firm submitted the copy of monograph of USP instead of justification and claimed that they follow Test 2 of monograph for dissolution testing of drug product, in which the acceptance criteria is again NLT 80%(Q) of the labelled claim of valsartan.
5.	3.2.P.2.2	Submit complete dissolution profile data in line with the decision of	Firm has submitted the complete data of comparative dissolution profile in accordance with the decision of 293rd meeting of Registration Board.

		293rd meeting of Registration Board.	
6.	3.2. P.5	• Justify why content uniformity test is not included in the finished product specification, further justify why content uniformity test was not performed during the stability studies.	Firm submitted the raw data sheet of content uniformity test, which has been performed while stability studies of drug product.

Decision: Approved.

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

515.	Name, address of Applicant / Marketing Authorization Holder	Variant Pharmaceuticals (Pvt.) Ltd
	Name, address of Manufacturing site.	Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqp Road District Sheikhupura.Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8628 dated 04/04/2022
	Details of fee submitted	PKR 30,000/-: dated 09/03/2022
	The proposed proprietary name / brand name	AMLOSARTAN 10/160mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains Amlodipin Besylate eq. to Amlodipine …..10mg Valsartan…….160mg
	Pharmaceutical form of applied drug	Film Coated Tablet.
	Pharmacotherapeutic Group of (API)	Calcium channel blocker & Angiotensin II recept blockers
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Exforge 10 mg/160 mg film-coated tablets b Novartis Europharm Limited,Vista Building Elm Park, Merrion Road.Dublin 4.Ireland USFDA Approved.
	For generic drugs (me-too status)	Exforge 10/160 mg tablets by by M/s Novart Pharmaceuticals Ltd, Reg. No. 047571
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020 General Tablet, General Capsule, General Sach and General dry powder injectable (pre-lyophilize

	Name and address of API manufacturer.	CADILA PHARMACEUTICALS LIMITED. (Amlodipine Besylate) 294, GIDC Industrial Estate, Ankleshwar-393 002 Gujarat. INDIA. Zhuhai Rundu Pharmaceutical Co., Ltd. (Valsartan No.6, North Airport Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province, 519041, P. R. of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general propertie solubilities, physical form, manufacturer description of manufacturing process and control impurities, specifications, analytical procedures ar its verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance ar drug product is submitted.
	Module III (Drug Substance)	Official monograph of Amlodipine Besylate ar Valsartan is present in USP/BP. The firm submitted detail of nomenclature, structure, gener properties, solubilities, physical form manufacturers, description of manufacturing proce and controls, tests for impurity & related substance specifications, analytical procedures and verification, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 month Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 month
	Module-III (Drug Product):	The firm has submitted detail of manufacturer description of manufacturing process and control impurities, specifications, analytical procedu (including dissolution testing at acidic and buff medium) and its verification studies, batch analys and justification of specification, reference standar container closure system and stability studies of dru product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been establishe against the innovator brand that is Exforg 10/160mg Tablet by M/s Novartis Pharmaceutica Ltd, Reg. No. 047571 by performing quality tes (Identification, Assay, Dissolution,). CDP has been performed against the same brand th is Exforge 10/160mg Tablet by M/s Novartis, Acid media (pH 1.2), Acetate buffer (pH 4.5) Phosphate Buffer (pH 6.8). The values for f1 and are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitte including linearity, range, accuracy, precisio specificity.
STABILITY STUDY DATA		

Manufacturer of API	CADILA PHARMACEUTICALS LIMITED. (Amlodipine Besylate) 294, GIDC Industrial Estate, Ankleshwar-393 002 Gujarat. INDIA. Zhuhai Rundu Pharmaceutical Co., Ltd. (Valsartan) No.6, North Airport Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province, 519041, P. R. of China		
API Lot No.	20AD096 (Amlodipine) 67820030604 (Valsartan)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	02-07-2021	10-07-2021	17-07-2021
Date of Initiation	09-07-2021	16-07-2021	22-07-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	AMLODIPINE BESLYLATE: Copy of GMP certificate No. 18101065 FDA INDIA issued by FDA INDIA valid till 18-10-202 VALSARTAN: Copy of GMP certificate No. GD20160649 FDA CHINA issued by FDA CHINA valid till 13-11-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.4111/2020/DRAP-AD-CD(I&E) dated 18/03/2020 is submitted wherei the permission to import different APIs includin AMLODIPINE BESYLATE & VALSARTAN for the purpose of test/analysis and stability studies is granted. • Invoice # CPL/BD/SAM/003/20-21 AD date 09 10-2020 FOR AMLODIPINE • Invoice # RD2020060101-1 AD date 23-07-202 FOR VALSARTAN
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

<table>
<tr><th>S.no.</th><th>Sections</th><th>Observations/Deficiencies/ Short-comings</th><th>Reply of the Firm</th></tr>
<tr><td>1.</td><td>3.2. S.4</td><td>• Provide detailed analytical procedures for the testing of both drug substance by drug product manufacturer.
• Provide analytical Method validation studies of drug substance amlodipine performed by the drug product manufacturer.</td><td>Firm has submitted analytical procedures used for testing of both drug substances along with analytical method verification reports.</td></tr>
<tr><td>2.</td><td>3.2. P.1</td><td>• Justify the choice of excipients in your formulation, since the excipients used are different from that of the innovator / reference product. Further justify how the formulation was developed without performing drug-excipient compatibility studies.</td><td>Firm has submitted the results of 6month real time stability data of drug product under the head of compatibility analysis sheet.</td></tr>
<tr><td>3.</td><td>3.2. P.2.2</td><td>Specify details including batch number and manufacturing date of the reference / comparator product against which pharmaceutical equivalence is performed.</td><td>Firm has submitted following details:
<table>
<tr><th>Brand name</th><th>Batch no.</th><th>Mfg Date</th><th>Exp Date</th><th>Manufacturer</th></tr>
<tr><td>Exforge (Reg.no.047571)</td><td>BYA65</td><td>04-2021</td><td>03-2024</td><td>Novartis Pakistan</td></tr>
</table></td></tr>
<tr><td>4.</td><td>3.2.P.2.2</td><td>Justify, the below 80% (Q) release of valsartan of test product in pH 6.8 medium with reference to the acceptance criteria of USP monograph.</td><td>Firm submitted the copy of monograph of USP instead of justification and claimed that they follow Test 2 of monograph for dissolution testing of drug product, in which the acceptance criteria is again NLT 80%(Q) of the labelled claim of valsartan.</td></tr>
<tr><td>5.</td><td>3.2.P.2.2</td><td>Submit complete dissolution profile data in line with the decision of 293rd meeting of Registration Board.</td><td>Firm has submitted the complete data of comparative dissolution profile in accordance with the decision of 293rd meeting of Registration Board.</td></tr>
<tr><td>6.</td><td>3.2. P.5</td><td>• Justify why content uniformity test is not included in the finished product specification, further justify why content uniformity test was not performed during the stability studies.</td><td>Firm submitted the raw data sheet of content uniformity test, which has been performed while stability studies of drug product.</td></tr>
</table>

Decision: Approved.

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

Cases of Apremilast tablets:

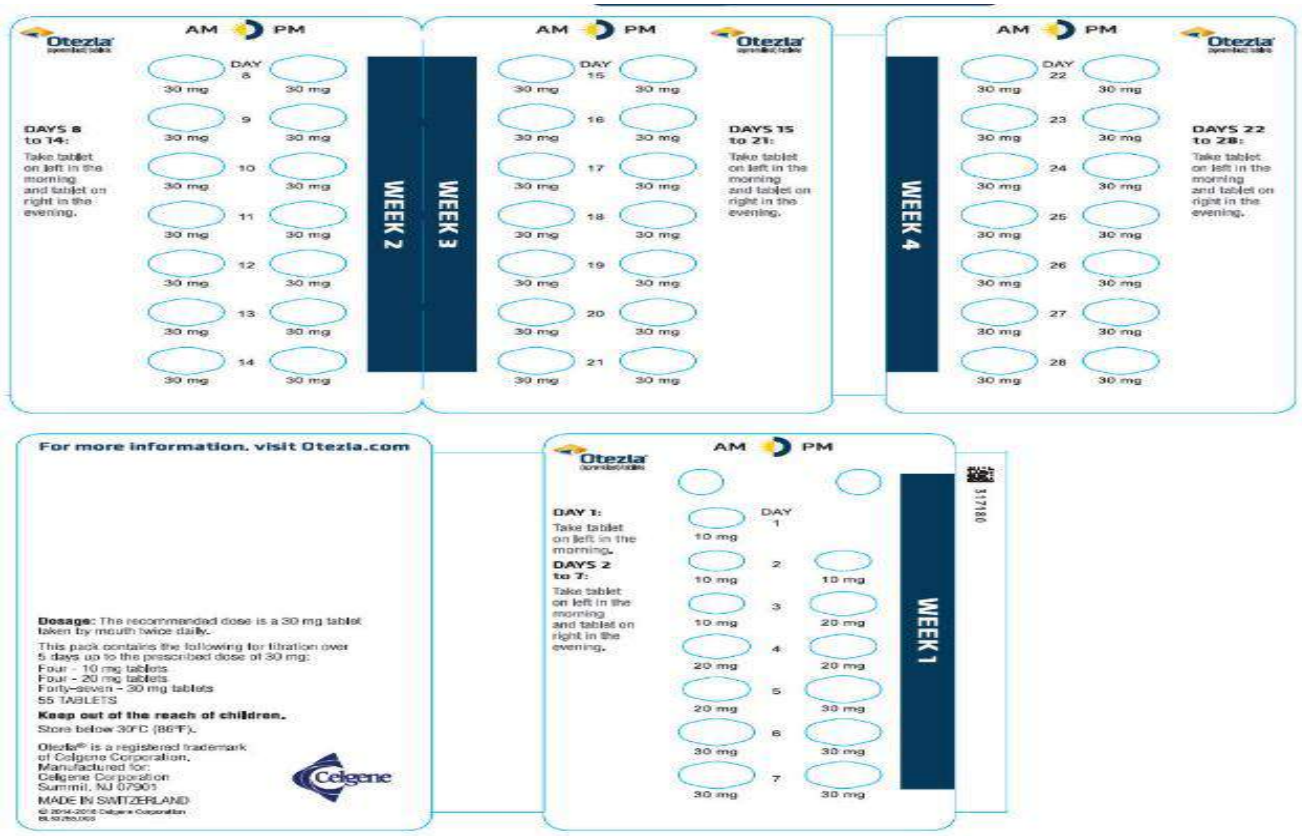
In compliance of decision of Authority taken in its 140th meeting, regarding the out of que consideration of registration applications of apremilast tablet, following are the cases of apremilast presented before the Board for its consideration please.

Discussion: Registration Board made thorough deliberations upon the presentations, dosage regimen and pack sizes of the innovator product. The innovator product i.e. Otezla tablet in USFDA recommended the initial dosage titration of OTEZLA from Day 1 to Day 5 is shown in the following table. Following the 5-day titration, the recommended maintenance dosage is 30 mg twice daily taken orally starting on Day 6. This titration is intended to reduce the gastrointestinal symptoms associated with initial therapy.

Dosage titration schedule in innovator brand:

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10mg	10mg	10mg	10mg	20mg	20mg	20mg	20mg	30mg	30mg	30mg

The requirement of co-blistering manufacturing facility was also discussed for presentation of tablet in similar display panel as of innovator product, one of the presentation of supply pack of innovator brand is as under:



According to the available literature of innovator brand, the titration pack is supplied in two different display panels i.e. 2-week starter pack or 28days starter pack, further separate packaging configuration of only 30mg tablet is also available for regular use.

Decision: Registration Board deliberated the matter in detail and decided as under:

i. **Approved to grant the registration of Apremilast Tablet 10mg, 20mg and 30mg with Innovator's Specifications. Furthermore, in order to standardize the drug as per dosage regimen of the innovator's drug product as approved by reference regulatory authorities, the Board decided that the manufacturers may adopt any of the following presentation for starter pack:**

   a. **Presentation / Pack size as per the Innovator's drug product i.e., Otezla Tablet approved by USFDA.**

OR

   b. **14 days Starter Pack:**

1st Blister (4 Tablets, each containing Apremilast 10mg)		
Day	**Morning (A.M.)**	**Evening (P.M.)**
1	**10mg Tablet**	**-**

2	**10mg Tablet**	**10mg Tablet**
3	**10mg Tablet**	**-**

2nd Blister (4 Tablets, each containing Apremilast 20mg)		
Day	**Morning (A.M.)**	**Evening (P.M.)**
3	**-**	**20mg Tablet**
4	**20mg Tablet**	**20mg Tablet**
5	**20mg Tablet**	**-**

3rd Blister (5 Tablets, each containing Apremilast 30mg)		
Day	**Morning (A.M.)**	**Evening (P.M.)**
5	**-**	**30mg Tablet**
6	**30mg Tablet**	**30mg Tablet**
7	**30mg Tablet**	**30mg Tablet**
4th Blister (14 Tablets, each containing Apremilast 30mg)		
Day	**Morning (A.M.)**	**Evening (P.M.)**
8-14	**30mg Tablet**	**30mg Tablet**

OR

c. 28 days Starter Pack:

1st Blister (4 Tablets, each containing Apremilast 10mg)		
Day	**Morning (A.M.)**	**Evening (P.M.)**
1	**10mg Tablet**	**-**
2	**10mg Tablet**	**10mg Tablet**
3	**10mg Tablet**	**-**

2nd Blister (4 Tablets, each containing Apremilast 20mg)		
Day	**Morning (A.M.)**	**Evening (P.M.)**
3	**-**	**20mg Tablet**
4	**20mg Tablet**	**20mg Tablet**
5	**20mg Tablet**	**-**

3rd Blister (5 Tablets, each containing Apremilast 30mg)		
Day	**Morning (A.M.)**	**Evening (P.M.)**
5	**-**	**30mg Tablet**
6	**30mg Tablet**	**30mg Tablet**
7	**30mg Tablet**	**30mg Tablet**

4th, 5th, 6th Blister (42 Tablets, each containing Apremilast 30mg)			
Blister	**Day**	**Morning (A.M.)**	**Evening (P.M.)**
4th	**8-14**	**30mg Tablet**	**30mg Tablet**
5th	**15-21**	**30mg Tablet**	**30mg Tablet**
6th	**22-28**	**30mg Tablet**	**30mg Tablet**

ii. A unit carton of 14 days starter pack shall contain:

- **a. Pouch-I: 1 blister of 4 tablets containing apremilast 10mg.**
- **b. Pouch-II: 1 blister of 4 tablets containing apremilast 20mg.**
- **c. Pouch-III: 2 blisters of 19 tablets containing apremilast 30mg (1 blister with 5 tablets and 1 blister with 14 tablets).**

OR

A unit carton of 28 days starter pack shall contain:

a. **Pouch-I: 1 blister of 4 tablets containing apremilast 10mg.**
b. **Pouch-II: 1 blister of 4 tablets containing apremilast 20mg.**
c. **Pouch-III: 4 blisters of 47 tablets containing apremilast 30mg (1 blister with 5 tablets and 3 blisters with 14 tablets each).**

iii. **Each blister shall be labelled in accordance with The Drugs (Labeling and Packing) Rules, 1986.**

iv. **Each type of blister (i.e. 10mg, 20mg or 30mg) shall be contained in a pouch which shall also contain information including brand name, strength, number of tablets and pouch number etc.**

v. **Outer unit carton shall contain all the information of blisters packed inside and shall be labelled in accordance with The Drugs (Labeling and Packing) Rules, 1986.**

vi. **For continuous use, Routine/ Maintenance Pack of 56 Tablets, each containing Apremilast 30mg, shall also be registered and marketed.**

vii. **The dosing schedule, conspicuously stating morning and evening doses, shall be printed on each blister. For this purpose, manufacturers shall submit proposed labeling / packaging of the product for approval of Chairman Registration Board before issuance of registration letter.**

	Name, address of Applicant / Marketing Authorization Holder	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.11093 dated 07-05-2022
	Details of fee submitted	PKR 75,000/- dated 04-2022
	The proposed proprietary name / brand name	Pixel tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each starter pack contains: PIXEL 10mg Tablet Each film coated tablet contains: Apremilast….10mg PIXEL 20mg Tablet Each film coated tablet contains: Apremilast….20mg PIXEL 30mg Tablet Each film coated tablet contains: Apremilast….30mg Tabros Specs.
	Pharmaceutical form of applied drug	PIXEL 10mg Tablet White to light yellow colour round film coated tablet plain on both sides. PIXEL 20mg Tablet Brown colour round film coated tablet plain on both sides PIXEL 30mg Tablet Brown colour round film coated tablet plain on both sides
	Pharmacotherapeutic Group of (API)	Anti-Psoriatic (PDE 4 Inhibitor)

	Reference to Finished product specifications	Tabros Specifications
	Proposed Pack size	STARTER PACK OF PIXEL (Apremilast) TABLETS (4's Tablets of 10mg, 4's Tablets of 20mg & 56's Tablets of 30mg)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OTEZLA tablet by M/s Celgene, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted on 07-04-2022
	Name and address of API manufacturer.	M/s Glenmark Life Sciences Limited, India A-80, MIDC, KURKUMBH, TAL.DAUND-413802,Dist. PUNE Zone 4, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per template provided in 293DRB meeting minutes. Firm has summarized information related to nomenclature, structure, general properties, isomerism, polymorphism, solubilities, physical form, manufacturers, description of manufacturing process and controls, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted data for facilities, equipments and regional information.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, isomerism, polymorphism, manufacturers, description of manufacturing process and controls, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: D3350116001 (82160888). D3350116002 (82161041). D3350116003 (82161086).
	Module-III (Drug Product):	Firm has submitted information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation

		of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is OTEZLA tablet 10mg, 20mg & 30mg by Celgene Corporation, USA by performing quality tests including Identification, water content, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is OTEZLA tablet by Celgene Corporation, USA in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, Detection limit, Quantitation limit, robustness, stability indicating.

STABILITY STUDY DATA

Manufacturer of API	M/s Glenmark Life Sciences Limited, India								
API Lot No.	83170813								
Description of Pack (Container closure system	STARTER PACK This pack contains the following for titration over 5days up to the prescribed dose of 30mg: Four (1x4's)- 10mg Tablets Four (1x4's)- 20mg Tablets Fifty-Six (4 x 14's)- 30mg Tablets All above are packed in Alu - Alu Blister.								
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH								
Time Period	Real time: 24 months Accelerated: 6 months								
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)								
Strength	PIXEL 10mg Tablet			PIXEL 20mg Tablet			PIXEL 30mg Tablet		
Batch No.	TR001-1/PIX	TR002-1/PIX	TR003-1/PIX	TR001-2/PIX	TR002-2/PIX	TR003-2/PIX	TR001-3/PIX	TR002-3/PIX	TR003-3/PIX
Batch Size	1100 tablets	1000 tablets	1000 tablets	1000 tablets	1000 tablets	1000 tablets	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019			05-2019			06-2019		
Date of Initiation	28-05-2019			30-05-2019			26/6/19	1/07/19	1/07/19
No. of Batches	03			03			03		

Administrative Portion

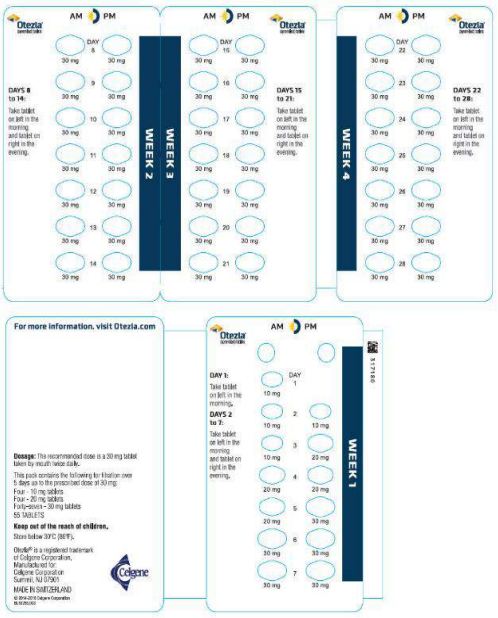
13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel: 1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board).

		2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate for M/s Glenmark life sciences, India The certificate is valid till 24th January 2023.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has imported 0.2Kg API consignment Glenmark life sciences, India, bearing invoice number F2000000116 dated July 28, 2018. ADC signed Form 6 & invoice is available. Form 3 and form 7 also available.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Observations/shortcomings	Reply of the firm
1.	3.2.S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s)"	Firm submitted the analytical verification report of drug substance
2.	3.2. P.2.2.1	It is evident from the comparative dissolution profile data that an expired batch of innovator brand has been used in all three strengths for comparison. The expiry date of Otezla tablet batch no.H02248A was Nov-20 and date of analysis mentioned on CDP report is 17/03/2021.Clarification is required in this regard	Firm submitted the reply in which it is stated that "Initially, they have been submitted CDP as per updated USFDA guideline with the specification of NLT 80(Q) in 45 minutes, these studies were conducted in sep-2020 at that time innovator sample was within the expiry. Later on,01 March 2021, they have received query from the DRAP on dissolution and in response of query, they again performed CDP in March 2021 with the outdated Innovator samples, because they cannot wait to procure the innovator samples from USA immediately, since it is time taking activity. Hence, on truthful ground realities they have been seen there is no significant change in results have been observed with the same samples, therefore they used similar innovator

			sample for CDP to fulfill the requirements of DRAP.
3.	3.2. P.5.1	Justify for setting the acceptance criteria of dissolution test other than adapted by innovator/reference product. The review report of innovator brand approved in USFDA revealed that the recommended dissolution criteria should be NLT (Q) in 30 minutes, while the dissolution criteria adapted for applied product was NLT 80%(Q) in 45 minutes.	

4.	3.2.P.7	The applied starter pack presentation mentioned in section 3.2.P.7 was consist of 4 Alu-Alu blisters of (30mg) each of 14 film coated tablet along with one Alu-Alu blister (10mg) of 4 film coated tablets as well as one Alu-Alu blister (20mg) of 4 film coated tablets packed in a unit carton. While as per the innovator brand the starter, pack is for 2 weeks which consist of 13-tablet blister titration pack containing:(4) 10-mg, (4) 20-mg, and (5) 30-mg tablets with an additional (14) 30mg tablets. Justify the rationality of your starter pack presentation with reference to the innovator.	Firm in the reply stated that "Review Report has considered as a Bench Mark "2-week starter pack", however, this is NOT FOR SALE, mentioned on innovator pack, the actual innovator commercial pack size 28 days. In 28 days, pack, innovator has presented in one blister 04-tablets 10mg,04-tablets 20mg and 05-tablets 30mg, and rest of other 3 strips are 14's x3, (30mg). Likewise, the same technology we don't have to keep simultaneously 10mg,20mg and 30mg in one strip. Nevertheless, we adapted same theme as innovator, accommodate, one Alu-Alu blister (10mg) of 4 film coated tablets as well as one Alu-Alu blister 20mg of 4 film coated tablets along with (30mg) 04 Alu-Alu blister in one-unit carton to make it symmetrical. The innovator and our pack only one difference innovator providing forty-seven tablets of 30mg, while we are providing fifty-six tablets. Presentation of display panel of 28 days starter pack of innovator Brand:  While the Applied pack presentation: 32-days starter Pack 04-Tablet Blister (10mg) 04-Tablets Blister 20mg With an additional (14's x4 = 56)30mg Tablets.

Decision: Approved registration of starter pack (1 pack only) with innovator's specifications as per details mentioned in above decision.

- **Registration letter will be issued after submission of revised limit of dissolution test in line with innovator product along with performance data of dissolution in compliance of new adapted dissolution limits. Further, Firm shall submit the fee of Rs. 7,500 for revision of specifications per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **The Board further decided that registration letter for apremilast 30mg (already approved) will be issued after approval of starter pack.**

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

Name, address of Applicant / Marketing Authorization Holder	M/s Crystolite Pharmaceuticals Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad.
Name, address of Manufacturing site.	M/s Crystolite Pharmaceuticals Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad.
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 17520 dated 15/06/2022
Details of fee submitted	PKR 75,000/-: dated 19/04/2022
The proposed proprietary name / brand name	APREMIST COMBO PACK (10MG, 20MG, 30MG TABLETS)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	APREMIST 10MG TABLETS Each Film Coated Tablet Contains: Apremilast ……10mg APREMIST 20MG TABLETS Each Film Coated Tablet Contains: Apremilast ……20mg APREMIST 30MG TABLETS Each Film Coated Tablet Contains: Apremilast ……30mg
Pharmaceutical form of applied drug	10 mg film-coated tablet (The tablets are pink, round, biconvex, film coated tablet, one side smooth and other is engraved with CRYSTO) 20 mg film-coated tablet (Brown, round, biconvex, film coated tablet, one side smooth and other is engraved with CRYSTO) 30 mg film-coated tablet (Beige Color, Round, Biconvex, One side smooth & other is engraved with "CRYSTO" Film Coated Tablets)
Pharmacotherapeutic Group of (API)	Antipsoriatic (Selective Immunosuppressant)
Reference to Finished product specifications	Innovator's specification

	Proposed Pack size	Combo Pack Contains: 10MG (4's), 20MG (4's), 30MG (4x14's) 56 Tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Otezla Tablet by M/s Amgen Inc, USFDA Approved.
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	Firm has provided the inspection report for renewal of DML conducted on 12-11-2018 & 02-01-2019
	Name and address of API manufacturer.	Apremist 10mg & 20mg Tablets Glenmark Life Sciences Limited Address: Plot No. A-80, MIDC, Kurkumbh, Tal-Daund, Dist. Pune - 413 802, India. Apremist 30mg Tablets Kaifeng Pharmaceutical (Group) Co., Ltd. No.1 Yunan Street, Kaifeng City, Henan Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Glenmark Life Sciences Limited Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (83151223, 83151300, 83151315) Kaifeng Pharmaceutical (Group) Co., Ltd. Stability study conditions:

		Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (HF140718, HF140610, HF140526)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Data for establishing Pharmaceutical equivalence by performing all the quality tests and comparative dissolution profile has been submitted against the comparator product "Otezla 10mg, 20mg & 30mg combo pack Tablet by Amgen Batch number H02495A
	Analytical method validation/verification of product	Protocols along with the complete data of validation studies are submitted.

STABILITY STUDY DATA			
Manufacturer of API	Apremist 10mg & 20mg Tablets Glenmark Life Sciences Limited Address: Plot No. A-80, MIDC, Kurkumbh, Tal-Daund, Dist. Pune - 413 802, India. Apremist 30mg Tablets Kaifeng Pharmaceutical (Group) Co., Ltd. No.1 Yunan Street, Kaifeng City, Henan Province, China		
API Lot No.	Glenmark Life Sciences Limited: 82190049 Kaifeng Pharmaceutical (Group) Co., Ltd.: HF151025 & HF151118		
Description of Pack (Container closure system)	Alu/Alu foil blister of 10mg (4's) tablets, are packed along with Alu/Alu foil blister of 20mg (4's) tablets, Alu/Alu foil blisters of 30mg (4x14's) tablets with patient information leaflet into card board outer carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Apremist 10mg & 20mg Tablets Real time: 6 months Accelerated: 6 months Apremist 30mg Tablets Real time: 24 months Accelerated: 6 months		
Frequency	Apremist 10mg & 20mg Tablets Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) Apremist 30mg Tablets Accelerated: 0,1,2,3,4,6,8,12,16,20,24 (Weeks) Real Time: 0,1,2,3,4,6,8,12,16,20,24,36,48 (Weeks), 18,24 (months)		
Batch No.	Apremist 10mg Tablets 004T21	Apremist 10mg Tablets 005T21	Apremist 10mg Tablets 006T21

	Apremist 20mg Tablets 007T21 Apremist 30mg Tablets 007T16	Apremist 20mg Tablets 008T21 Apremist 30mg Tablets 011T16	Apremist 20mg Tablets 009T21 Apremist 30mg Tablets 012T16
Batch Size	600 tab for each strength	600 tab for each strength	600 tab for each strength
Manufacturing Date	Apremist 10mg Tablets 10-2021 Apremist 20mg Tablets 10-21 Apremist 30mg Tablets 04-2016	Apremist 10mg Tablets 10-2021 Apremist 20mg Tablets 10-21 Apremist 30mg Tablets 04-2016	Apremist 10mg Tablets 10-2021 Apremist 20mg Tablets 10-21 Apremist 30mg Tablets 04-2016
Date of Initiation	Apremist 10mg Tablets 004T21 (09.10.2021) Apremist 20mg Tablets 007T21 (13.10.2021) Apremist 30mg Tablets 007T16 (07.04.2016)	Apremist 10mg Tablets 005T21 (10.10.2021) Apremist 20mg Tablets 008T21 15.10.2021 Apremist 30mg Tablets 011T16 (11.04.2016)	Apremist 10mg Tablets 006T21 (12.10.2021) Apremist 20mg Tablets 009T21 16.10.2021 Apremist 30mg Tablets 012T16 (12.04.2016)
No. of Batches	03 batches for each strength		

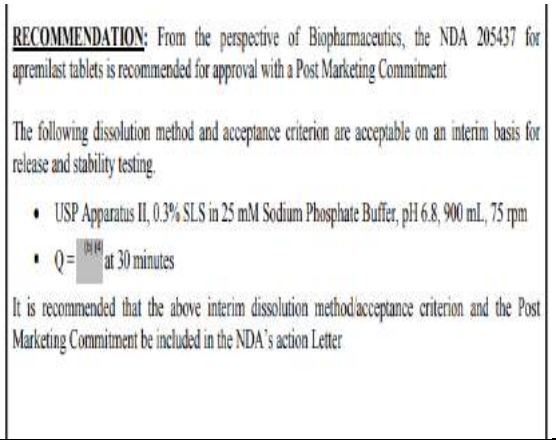
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred last onsite panel inspection for Dapazin-M 5/1000 mg Tablet Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin 5mg & Metformin HCl 1000mg which was approved in 307th meeting of Registration Board
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Glenmark Life Sciences Limited Copy of DML certificate No. MH/102855 issued by Food & Drugs Administration (Maharashtra State) valid till 31/12/2023. Copy of GMP certificate No. 6104231issued by Food & Drugs Administration (Maharashtra State) valid till 24/01/2023. Kaifeng Pharmaceutical (Group) Co., Ltd.

		Copy of DML certificate No. 20150031 issued by FDA valid till 31/12/2025. Copy of GMP certificate No. HA20190069 issued CFDA valid till 28/09/2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Glenmark Life Sciences Limited Firm has submitted copy of invoice (invoice# F32200000700) cleared by DRAP Islamabad office dated 28-09-2021 specifying import of Desloratadine. Firm has submitted undertaking that firm has purchased commercial quantity of Desloratadine from manufacturer Glenmark Life Sciences Limited. Along with Desloratadine supplier has send free of cost sample of Apremilast and Apremilast working standard. Firm has applied ADC of only Desloratadine dated 28 Sep 2021 Kaifeng Pharmaceutical (Group) Co., Ltd. Firm has submitted copy of invoices (No.CIN20151117D01 & CIN20151210D01) cleared by DRAP Islamabad office dated 22-12-2015 specifying import Of 40gm Apremilast & 20gm Apremilast respectively
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.No.	Deficiencies/Shortcomings	Reply of the Firm
1.	Drug Substance Manufacturer (M/s. Glenmark Life Sciences, India)	
	a) Submit the evidence of availability of HPLC equipped with quaternary gradient pumps, variable wavelength UV detector with data recorder and integrator software by the drug product manufacturer, since the said equipment has been used as evident from the analytical method verification report of drug substance from drug product manufacturer.	Firm has submitted revised analytical procedure in which HPLC equipped with binary gradient pump has been used.
	b) Justification is required for not performing the enantiomeric purity test while analysing the quality of drug substance by drug product manufacturer. Since, it is the critical test for apremilast because the active substance exhibits stereoisomerism due to presence of a single chiral centre, with the (S)-enantiomer being pharmacologically active.	Firm has submitted the procedure of enantiomeric purity test along with revised batch analysis report.
2.	c) According to the assay procedure submitted in section 3.2.S.4.2 by drug product manufacturer, the run	Firm has submitted revised analytical procedure and following chromatographic conditions has been mentioned:

	time should be 15minutes, injection volume should keep at 10µl and the apremilast elutes at retention time of about 7 minutes. While the chromatogram of verification report from drug product manufacturer revealed that the run time was 20min, injection volume kept at 20µl and the main peak elute at 14.319 minutes. Clarification is required in this regard.	Flow rate: 1.0ml/min Detection wavelength: UV 220nm Injection volume :20µl Retention time and total run time has not been mentioned in the revised procedure.
3.	Drug Substance Manufacturer (M/s. Kaifeng Pharmaceutical Group, China)	
	a) Justify of using different assay method for analysis of drug substance from that given by drug substance manufacturer.	Firm has submitted revised analytical procedure without any justification.
	b) Analytical method verification of drug substances performed by drug product manufacturer, imports from two different sources exhibit same results, justify.	Firm has submitted revised analytical method verification report for both drug substance which are import from two different sources.
	c) Justification is required for not performing the enantiomeric purity test while analysing the quality by drug product manufacturer. Since, it is the critical test for apremilast because the active substance exhibits stereoisomerism due to presence of a single chiral centre, with the (S)-enantiomer being pharmacologically active	Firm in their reply stated that "we have not performed enantiomeric purity test because we have not purchased impurity standards along with the raw material.
	Drug Product	
4.	Justify the performance of comparative dissolution profile of using UV method while the procedure of dissolution testing specified in section 3.2.P.5.2 stated that the dissolution test should be performed on HPLC.	Firm has submitted revised analytical procedure in which the method for performance of dissolution test both on HPLC and UV has been included.
5.	Scientific justification required that, how an active substance classified as having low solubility and low permeability according to Biopharmaceutical Classification System (i.e. BCS Class 4) release more than 85% within 20 minutes in all the three BCS medium as evident from the submitted CDP report of three strengths.	Firm in their reply stated that "we have done CDP of our all three strengths with innovator product at three different pH. The release pattern of our product is comparable with innovator as mentioned in CDP report. The drug products show similar behavior in three different pH mediums.
6.	Justify the performance of validation of assay procedure of using UV method since the analytical procedure given in section 3.2.P.5.2 mentioned that the assay be performed on HPLC.	Firm in their reply stated that "we have used HPLC method for the performance of validation of assay procedure instead of UV method. The word absorbance of peak was mistakenly written on the report, revised report has submitted.
7.	Justify for setting the acceptance criteria of dissolution test other than adapted by innovator/reference product. The review report of innovator brand approved in USFDA revealed	Firm revised the dissolution acceptance criteria in accordance with innovator product i.e. NLT 80% (Q) in 30 minutes.

<table>
<tr><td></td><td>that the recommended dissolution criteria should be NLT (Q) in 30 minutes, while the dissolution criteria adapted for applied product was NLT 80%(Q) in 45 minutes.
Specify the acceptance criteria of dissolution test in term of Q value and with the time point at which NLT 80% should be achieved, since the specification given in section 3.2.P.5.1 and batch analysis report in section 3.2.P.5.4 did not mentioned the time point.</td><td>Further the dissolution results of stability study were also within limits of revised acceptance criteria.
 
<u>RECOMMENDATION</u>: From the perspective of Biopharmaceutics, the NDA 205437 for apremilast tablets is recommended for approval with a Post Marketing Commitment
The following dissolution method and acceptance criterion are acceptable on an interim basis for release and stability testing.
• USP Apparatus II, 0.3% SLS in 25 mM Sodium Phosphate Buffer, pH 6.8, 900 mL, 75 rpm
• Q= [redacted] at 30 minutes
It is recommended that the above interim dissolution method/acceptance criterion and the Post Marketing Commitment be included in the NDA's action Letter</td></tr>
<tr><td>8.</td><td>The applied starter pack presentation mentioned in section 3.2.P.7 consist of 4 Alu-Alu blisters of (30mg) each of 14 film coated tablet along with one Alu-Alu blister (10mg) of 4 film coated tablets as well as one Alu-Alu blister (20mg) of 4 film coated tablets packed in a unit carton. While as per the innovator brand the starter, pack is for 2 weeks which consist of 13-tablet blister titration pack containing:(4) 10-mg, (4) 20-mg, and (5) 30-mg tablets with an additional (14) 30mg tablets. Justify the rationality of your starter pack presentation with reference to the innovator.</td><td>Firm in their reply stated that we have applied pack size 10mg (4's),20mg (4's),30mg (4x14's) the reason for applying this pack size is because our individual product apremist 30mg is already registered with pack size (4x14's) i.e. 56 tablets and the pricing done by DRAP is also for the same pack size. Therefore just because of the pricing done by DRAP we have decided to provide product in market with pricing of 56 tablets of 30mg strength along with free of cost 4 tablets of 10mg and free of cost 4 tablets of 20mg.</td></tr>
<tr><td>9.</td><td>Justify the quantity of apremilast used for the development of trial batches with reference to its potency adjustment and water content calculation, since the submitted BMR of all three strength did not mentioned the calculation of dispensing amount of active ingredient per unit.</td><td>Firm submitted the calculation in which factor 1.000300 for calculation.</td></tr>
<tr><td>10.</td><td>Weight of tablet of all three strengths of innovator brand increase with empirical ratio as per the review report of USFDA, while the weight of tablet of all three applied strength varies irrespective of their increase quantity of active ingredient.</td><td>Firm replied that "we have followed innovator product qualitatively and not by quantitatively".

In innovator product weight of tablet increase with the empirical ration i.e.
<table><tr><td>10mg</td><td>20mg</td><td>30mg</td></tr><tr><td>104.00</td><td>208.00</td><td>312.00</td></tr></table></td></tr>
<tr><td>11.</td><td>Scientific justification is required regarding the variation of retention time of apremilast observed in the chromatograms of all three strengths, it varies from 11 minutes till 22 minutes, justify it with system suitability report.</td><td>Firm in their reply stated that "we have submitted data of 6months of apremist 10mg &20mg and 2 years for apremist 30mg ,so the test performed in different time period may influenced by the conditions that is change in lots of chemical used, mobile phase preparations, analyst and column conditions.</td></tr>
<tr><td>12.</td><td colspan="2">Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
Firm submitted the following information:
<table><tr><td>Lot No.</td><td>Batch of Drug Product</td></tr></table></td></tr>
</table>

	Apremist 10mg tablet	
	82190049 from Glenmark Life Sciences Ltd.	004T21 004T22 004T23
	Apremist 20mg tablet	
	82190049 from Glenmark Life Sciences Ltd.	007T21 008T21 009T21
	Apremist 30mg tablet	
	HF151118 from Kaifing Pharmaceuticals Co. Ltd.	007T16
	HF151025 from Kaifing Pharmaceuticals Co. Ltd.	011T16
	HF151025 from Kaifing Pharmaceuticals Co. Ltd.	012T16
13.	Justify, how the batch no. H02248A of innovator product otezla tablet that was manufactured in 2021 according to the expiry date of 05-2023 could be available for the performance of Comparative dissolution testing back in the year 2018, since as per the submitted CDP report of apremist 30mg Tablet analysis has been done in 2018. Firm replied that we are again submitting the CDP report of Apremist 30mg tablet in which expiry date of innovator product is mentioned as Nov.2020. Otezla 30mg Tablet Batch no. H02248A Exp date : Nov-2020	

Decision: Approved registration of starter pack (1 pack only) with innovator's specifications as per details mentioned in above decision

- **Registration letter will be issued after submission of revised and scientifically rationale CDP report by keeping in view the BCS classification of active ingredient.**
- **Firm shall submit the fee of Rs. 7,500 for revision of specifications per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The Board further decided that registration letter for apremilast 30mg (already approved) will be issued after approval of starter pack.**

Cases of Diclofenac Potassium:

In compliance of decision of Authority taken in its 140th meeting, regarding the out of que consideration of registration applications of diclofenac potassium and famotidine, following are the registration applications of diclofenac potassium received in DRAP were evaluated out of que and shortcoming letters have communicated to the firms but reply has not received yet, cases presented before the Board for its consideration please.

516.	Name, address of Applicant / Marketing Authorization Holder	M/s Quaper Pvt. Ltd.
	Name, address of Manufacturing site.	26-A Small Industrial Estate Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18756 dated 28-06-2022
	Details of fee submitted	PKR 30,000/-: dated
	The proposed proprietary name / brand name	KAYMAX Sachet 50 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Diclofenac Potassium 50 mg
	Pharmaceutical form of applied drug	Sachet
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory Drug (NSAID)
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	1×10's & 1×30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Voltfast 50 mg Sachet by Novartis Pharma AG, Basel, Switzerland USFDA Approved.
	For generic drugs (me-too status)	Voltfast 50 mg Sachet by Novartis Pharma
	GMP status of the Finished product manufacturer	GMP certificate No. 161/2019-DRAP(AD732485-5132) Copy of GMP certificate Issued by DRAP is attached.
	Name and address of API manufacturer.	Name of API: Diclofenac Potassium M/s AARTI DRUGS LIMITED (G-60). PLOT NO. G-60, MIDC, TARAPUR, BOISAR TAL.PALGHAR, DIST: THANE.MAHARASHTRA. INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Monograph of Diclofenac Potassium exist in USP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Diclofenac Potassium Batches: (DFK/10070024, DFK/10070025, DFK/10070026)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.	
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Voltfast 50 mg Sachet by Novartis Pharma AG, Basel, Switzerland by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Voltfast 50 mg Sachet by Novartis Pharma AG, Basel, Switzerland. in Acid media 0.1N HCl (pH 1.2), Buffer (pH 4.5) & Buffer (pH 6.8). The values for f2 are in the acceptable range.	
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API	Name of API: Diclofenac Potassium M/s AARTI DRUGS LIMITED (G-60). PLOT NO. G-60, MIDC, TARAPUR, BOISAR TAL.PALGHAR, DIST: THANE.MAHARASHTRA. INDIA.		
API Lot No.	Diclofenac Potassium Batch No.DFK/10120182		
Description of Pack (Container closure system)	Aluminum foil sachet packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1/21	T2/21	T3/21
Batch Size	2000 Sachet	2000 Sachet	2000 Sachet
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	07-05-2021	07-05-2021	07-05-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	For Diclofenac Potassium Copy of GMP certificate No.NEW-WHO-GMP/CERT/KD/84387/2019/11/29412 issued by Food & Drug administration Maharashtra state India.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted	

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm informed that their HPLC system has not in compliant with 21CFR SOFTWARE.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.No.	Deficiencies/ Short-comings	Reply of the Firm
1.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s)"	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer.
2.	Justification is required for not including the microbial enumeration test, test for specified microorganism and pH determination test while analysis of trial batches of drug product, since these tests are the part of USP monograph of diclofenac potassium for oral solution.	Firm in their reply stated that: "Microbial & Ph determination tests as specified in USP monograph for diclofenac potassium for oral solution were performed during stability studies of all three trial batches but erroneously it could not be submitted with dossier. We are submitting the microbial test report.
3.	Justify for not performing the test for determination of pH while stability study of trail batches of drug product.	Firm in their reply stated that "pH determination test as specified in USP monograph for diclofenac potassium for oral solution were performed during stability studies of all three trial batches but erroneously it could not be submitted with dossier in the stability summary sheet. Correct summary report are submitted.

Decision: Approved with USP specifications.

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

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

517.	Name, address of Applicant / Marketing Authorization Holder	M/s. Sunshine Pharmaceuticals Emanabad, G.T. Road, Gujranwala
	Name, address of Manufacturing site.	M/s. Sunshine Pharmaceuticals Emanabad, G.T. Road, Gujranwala
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No.11602 dated 13-05-2022
	Details of fee submitted	PKR 30,000/-: dated 05-04-2022
	The proposed proprietary name / brand name	Detran-P 50 mg Film coated Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Diclofenac Potassium……50 mg
	Pharmaceutical form of applied drug	Oral tablet
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory Drug (NSAID)
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Artinil-K Tablet of M/s. Global Pharmaceuticals (Reg.no.005982)
	GMP status of the Finished product manufacturer	Copy of GMP certificate Issued by DRAP is attached.
	Name and address of API manufacturer.	Name of API: Diclofenac Potassium M/s. Henan Dongtai Pharm Co. Ltd. East Changhong Road,Tangyin Henan,China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Monograph of Diclofenac Potassium exist in BP pharmacopiea. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Diclofenac Potassium Batches: (131118-5, 131118-6, 131118-7)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator brand that is Diclorep 50 mg tablet by M/s. Sami Pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand in Acid media 0.1N HCl (pH 1.2), Buffer (pH 4.5) & Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Name of API: Diclofenac Potassium M/s. Henan Dongtai Pharm Co. Ltd. East Changhong Road,Tangyin Henan,China		
API Lot No.	Diclofenac Potassium Batch No. 20200329,20200330,20200331		
Description of Pack (Container closure system)	Detran-P Tablets are packed in Alu-PVC packing.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-001	Trial-002	Trial-003
Batch Size	8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	01-06-2021	01-06-2021	01-06-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	For Diclofenac Potassium Copy of GMP certificate No. HA20170001 issued by China Food and Drug Administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.No.	Deficiencies/ Short-comings	Reply of the Firm

1.	Provide compatibility studies of the drug Substance(s) with excipients as the qualitative composition of the formulation is not similar to innovator / reference product in section 3.2. P.2.1.1.	Firm submitted the summary report of compatibility testing study in which it was stated that FTIR spectral and HPLC analysis showed that there is no appearance or disappearance of any characteristic peaks of pure drug Diclofenac Potassium and in the physical mixture of all other excipients which confirms the absence of chemical interaction between drug substance and excipient.
2.	As per the USP monograph of diclofenac potassium tablet the recommended dissolution medium should be Simulated intestinal fluid (without enzyme), while the dissolution medium of drug product mentioned in section 3.2. P.5.2 was buffer solution pH 6.8. Justify for not complying the USP monograph in terms of selection of dissolution medium.	Firm in their reply stated that in analytical testing method the word simulated intestinal fluid was missing due to typographical error. Correct copy of analytical procedure has resubmitted. Further, the firm stated, we have used exactly same composition of dissolution medium as specified in USP (Intestinal Fluid, simulated) as evident from the submitted analytical procedure. However, USP monograph do not specify the composition of dissolution medium. Reference literature revealed that the pH of simulated intestinal fluid is between 6.50-6.60 (25 °C, after dilution)
3.	According to the dissolution data of stability batches of drug product more than 95% drug release within 60 minutes, then justify the setting of broader acceptance criteria for dissolution testing i.e. NLT 75% within 60 minutes. Further, the acceptance criteria of dissolution recommended by USP is in term of Q value, justify for not adapting the acceptance limit with the Q value.	Firm rectify the acceptance limit of dissolution test in terms of Q value and revised the criteria to "NLT 75% (Q) of the labeled amount dissolved in 60 minutes." Further, the firm did not give any justification of setting of broader acceptance criteria for dissolution testing i.e. NLT 75% within 60 minutes, despite of achieving 95% drug release within 60 minutes.

Decision: Approved with USP specifications.

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

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

518.	Name, address of Applicant / Marketing Authorization Holder	M/s. Batala Pharmaceuticals 23/B, Small Industrial Estate No.2 Gujranwala
	Name, address of Manufacturing site.	M/s. Batala Pharmaceuticals 23/B, Small Industrial Estate No.2 Gujranwala
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.1162 dated 18-01-2022
	Details of fee submitted	PKR 30,000/-: dated 15-12-2021

	The proposed proprietary name / brand name	Beflam 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sugar-coated tablet contains: Diclofenac Potassium……50 mg
	Pharmaceutical form of applied drug	Oral tablet
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory Drug (NSAID)
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Ariflam Tablet of M/s. Aries Pharmaceuticals (Reg.no.054526)
	GMP status of the Finished product manufacturer	Copy of GMP certificate not attached.
	Name and address of API manufacturer.	M/S Aarti Drugs Limited (G-60). Plot No. G-60, Midc, Tarapur, Boisar Tal. Palghar, Dist:Thane.Maharashtra. India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Monograph of Diclofenac Potassium exist in USP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Diclofenac Potassium Batches: (DFK/10070024, DFK/10070025, DFK/10070026)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator brand that is Caflam 50mg tablet by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).

		CDP has been performed against the same brand in Acid media 0.1N HCl (pH 1.2), Buffer (pH 4.5) & Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/S Aarti Drugs Limited (G-60). Plot No. G-60, Midc, Tarapur, Boisar Tal.Palghar, Dist: Thane. Maharashtra. India.		
API Lot No.	Diclofenac Potassium Batch No. DFK/18070058		
Description of Pack (Container closure system)	Tablets are packed in Alu-PVC packing.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DP21-001	DP21-002	DP21-003
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	01-06-2021	01-06-2021	01-06-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	For Diclofenac Potassium Copy of GMP certificate No. HA20170001 issued by China Food and Drug Administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.No.	Deficiencies/ Short-comings	Reply of the Firm
1.	Submit specifications as well as analytical method of drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm submitted the specification and analytical procedure of drug substance in accordance with USP.

2.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s)"	Firm submitted the verification report of drug product instead of drug substance as evident from the sample preparation of submitted report.
3.	Composition of drug product given in section 3.2.P.1 mentioned chloroform in the sugar-coating material, please elaborate the role of chloroform in the applied composition and provide scientific rational of its usage, along with the international literature reference.	Firm in their reply stated that "it was clerical mistake we are using IPA 70% as an organic solvent instead of chloroform for dissolving waxes.
4.	Provide compatibility studies of the drug Substance(s) with excipients as the qualitative composition of the formulation is not similar to innovator / reference product in section 3.2. P.2.1.1.	Firm in their reply stated that we have done placebo analysis in method verification in section 3.2.S.4.3,which did not show any interference of excipients with drug substance.
5.	Provide results of all quality test specify in the USP monograph of diclofenac potassium tablet to establish the pharmaceutical equivalence between reference and test product since the results are not mentioned.	Firm submitted the pharmaceutical equivalence report with caflam 50mg Tablet of M/s. Novartis with the result of assay, dissolution and disintegration.
6.	Justify how your product is comparable to reference product when the similarity factor f2 was below 50 as evident from the submitted CDP report of drug product.	Firm submitted the revised CDP report without any justification.
7.	BMR of drug product revealed the source of active ingredient was China, while, as per the S-part of CTD dossier, source of drug substance was AARTI Drug Limited, India, clarification is required in this regard.	Firm in their reply stated that it was mistakenly written China in BMR, correct copy of BMR has submitted.
8.	Scientific justification is required for using completely different method for assay of drug product then specified in USP monograph. Similarly, the analytical procedure verified in section 3.2.P.5.3 was also not in accordance with the method of assay recommended by USP monograph of diclofenac potassium tablet.	Firm submitted the reply that it was a clerical mistake that was submitted in section 3.2.P.5.3.Further, they stated that "we have performed all test during stability study in accordance with USP monograph. But, firm did not submit any documented evidence neither submitted the correct procedure. Further, the raw data sheet of stability data submitted in the reply again revealed that the assay procedure was not in accordance with USP in terms of chromatographic condition and the calculations.
9.	In section 1.5.6 you have specified that the pharmacopoeial reference of drug product was USP while in section 3.2.P.5 it is mentioned that the product complies inhouse specification, clarification is required either drug product complies pharmacopoeial reference or the in-house specification.	Firm stated that their drug product comply USP specification and they rectified the information in section 3.2.P.5.
10.	Provide detailed composition and preparation method of simulated intestinal fluid that is the recommended dissolution medium of diclofenac potassium tablet.	Firm submitted the dissolution medium details according to which pH 6.8 buffer medium has been prepared under the head of simulated intestinal fluid.

11.	Clarify the acceptance criteria of dissolution in term of time point at which NLT 75% should be achieved, as the time point has not mentioned on stability data sheet. Further set the acceptance criteria of dissolution in term of Q, since the USP monograph specify the limit with Q value i.e. NLT 75% (Q) of the labeled amount of diclofenac potassium dissolved.	Firm submitted the document which concluded that value of Q is 75% at time T 30 minutes. Firm neither correct the specification in section 3.2 P.5.1 nor in stability summary sheet.
12.	• Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide Reference of previous approval of applications with stability study data of the firm (if any) • Documents for the procurement of API with approval from DRAP (in case of import). • Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm submitted the COA of API of batch no. DFK/11010013 along with documented evidence of procurement of API. Further, firm submitted the audit trail report and digital data logger record.

Decision: Approved. Firm shall submit following before issuance of registration letter:

- **Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.**
- **Submission of revised method for assay testing of drug product in accordance with USP monograph of "Diclofenac potassium tablet" and accordingly performance of assay in compliance with USP on next time point of stability.**
- **Submission of revised dissolution limits in terms of %age released and time point from that recommended by the US FDA for innovator product and in compliance of USP monograph. Further, performance of dissolution testing in line with revised specification on next time point.**
- **Firm shall submit the fee of Rs. 7,500 for revision of specifications per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Cases of Form 5-F

519.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11065 dated 27/08/2021
	Details of fee submitted	PKR 75,000/-: dated 06/07/2021

	The proposed proprietary name / brand name	BISTIN 2.5mg/ml Oral Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Bilastine……2.5mg
	Pharmaceutical form of applied drug	Clear colorless to slightly colored Oral Solution
	Pharmacotherapeutic Group of (API)	Antihistamines ATC Code: RO6AX29
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	60ml & 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ilaxten / Bilaxten 2.5mg/ml oral solution M/s. Menarini International Operations Luxembourg S.A Spain Approved.
	For generic drugs (me-too status)	Not applicable
	GMP status of the Finished product manufacturer	GMP certificate issued dated: 11-08-2020
	Name and address of API manufacturer.	Virupaksha Organics Limited Address: Survey No. 10 Gaddapototharam Village Jinnaram, Mandal, Sangareddy District – 502319, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ABSTC0120001, ABSTC0120002, ABSTC0120003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, individual impurity and total impurity, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	It may please be noted that despite of our contacting M/s. Menarini Farmaceutica Internazionale SRL as well

		as local distributor, we could not obtain samples for conducting Pharmaceutical Equivalence. Due to the above fact w.r.t. its procurement, we are unable to perform Pharmaceutical Equivalence but despite of that we have considered and ensured that our formulation comply with the innovator & all our quality tests i.e. Identification, Assay, pH, Preservatives test, Degradation products and Microbial Enumeration Test comply the references/general guidelines and validated as per USP guidelines which ensures the quality and safety of our product CDP not applicable
	Analytical method validation/verification of product	Method validation studies have submitted including Linearity, Accuracy, Precision including Repeatability & Intermediate Precision, Robustness and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	Virupaksha Organics Limited, Telangana India		
API Lot No.	ABSNC1119001		
Description of Pack (Container closure system)	Amber Glass Bottle packed in unit carton (60ml & 120ml)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1,2,3,4 & 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	4 Liters	4 Liters	4 Liters
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	03-4-2020	03-4-2020	03-4-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Reference of our last onsite panel inspection for instant dosage form conducted during last three years LAGITA Double Action Suspension (Sodium Alginate + Sodium Bicarbonate + Calcium Carbonate) 500mg + 213mg + 325mg on 30th January 2020 The inspection report confirms following points The HPLC software is 21CFR Compliant 1. Audit trail on the testing reports is available. 2. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. 3. Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 5884/E1/2018 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana valid till 27/03/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (Invoice# AEX/085/2019-20 dated 27th November 2019

		with received quantity i.e. 400gm) for the purchase of Bilastine from M/s Virupaksha Organics Ltd. India with attestation of DRAP dated 03-12-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

Sr.no.	Shortcomings/Deficiencies	Response of the Firm
1.	Provide Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin since the submitted GMP certificate was valid till 2021.	Firm has submitted the copy of GMP certificate of drug substance manufacturer i.e. M/s. Virupaksha Organic Limited, Telangana state which is valid up till 29/01/2022.
2.	Justification is required for not performing the powder x-ray diffraction test by drug product manufacturer to confirm the polymorphic state of drug substance, since the bilastine has three different polymorphic forms. Further, the test has been included in the COA of the drug substance manufacturer.	Since, the testing facility of P-XRD is not available in Pakistan therefore we rely on drug substance manufacturer COA.
3.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm submitted preservative effectiveness studies of drug product.
4.	Justification is required for not performing compatibility studies of excipient with active ingredient, since the solubilizing agent of innovator is betadex and you have using β-Cyclodextrin sulfobutylether, sodium salt as a solubilizer.	Firm submitted the API- Excipient compatibility study report of bilastine oral solution.
5.	Provide data of pharmaceutical equivalence against the innovator product to justify your formulation development as per the requirement of section 3.2. P.2.2.1.	Firm submitted the reply that the reference product is not available in Pakistan, they have tried to arrange it from the country of origin but unfortunately not succeeded.

Decision: Deferred for submission of pharmaceutical equivalence report against the innovator drug product.

520.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.23863 dated 31-08-2021
	Details of fee submitted	PKR 30,000/-dated 29-07-2021 slip no. 5849810042
	The proposed proprietary name / brand name	Solidow Tablets 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Solifenacin Succinate ……10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-muscarinic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	10's & 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product is registered in FDA-USA, with brand name "VESICARE TABLET" by Astellas Pharma US, Inc.
	For generic drugs (me-too status)	Solifen Tablets 10mg by Getz Pharma (Registration No. 061203)
	GMP status of the Finished product manufacturer	GMP certificate issued 11-6-2020
	Name and address of API manufacturer.	Zhejiang Guobang Pharmaceuticals Co., Ltd. Address: No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (170501,170502,170503)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls,

		impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Innovator product that is VESICARE TABLETS 10mg by Astellas Pharma by performing quality tests (Identification, Disintegration, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is VESICARE TABLETS 10mg by Astellas Pharma, in Acid media (pH 1.2) F2= 63.1, Acetate buffer (pH 4.5) F2 =71.1 & Phosphate Buffer (pH 6.8) F2=54.6. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Guobang Pharmaceuticals Co., Ltd. Address: No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, PR China.		
API Lot No.	2011000080 (200501)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2x5's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1395-S	NPD-T-1429-S	NPD-T-1430-S
Batch Size	1500 tablets	5000 tablets	5000 tablets
Manufacturing Date	17-03-2021	09-04-2021	09-04-2021
Date of Initiation	21-04-2021	21-04-2021	21-04-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Empator Tablets 10mg which was approved in 291st Meeting of Registration Board held on 2nd - 4th September 2019. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML for Zhejiang Guobang Pharmaceuticals Co., Ltd. issued by Zhejiang Food and Drug Administration & valid up to 08-12-2024 is submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# GBPH2020-2023) Dated: 02-11-2020 from Zhejiang Guobang Pharmaceuticals Co., Ltd. cleared by DRAP Karachi office dated 03-11-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks OF Evaluator:		
Decision: Approved with innovator's specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility.		

Finished import product received on Form 5-F:

521.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block ''C'', Faisal Town Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-016174-D Address: 793-D, Block-C, Faisal Town Lahore Address of Godown: NA Validity: 06. Feb.2022 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Original legalized COPP (Certificate# DA/6-110/2016/3300 issued on 01-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. GMP: Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also, Renewal certificate is submitted (Certificate No. DA/6-110/06/4950).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited.

		The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan. The authorization letter is valid till June, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.16561 Date:15.06.2021
	Details of fee submitted	PKR: 100,030/- Date: Dec-2020
	The proposed proprietary name / brand name	Pazonix 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains Pazopanib Hydrochloride INN….200mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	30’s (HDPE Bottle)
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Votrient 200mg Tablet
	For generic drugs (me-too status)	Votrient (Novartis)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Ace bright (India) Pharma Private Limited Address: No. 77D &116/117, KIADB Industrial Area Jigani, Bangalore - 560 105 Karnataka, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container

		closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 12 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Votrient 200mg (Novartis) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:

Sr.no.	Shortcomings/Deficiencies	Response of the Firm
1.	Submit data of analytical Method verification studies including specificity, accuracy and repeatability (method precision).	Firm has submitted analytical method validation studies of drug substance performed by drug product manufacturer.
2.	Justify acceptance criteria set for dissolution test i.e. NLT 70% (Q) in 60 minutes, which is not as per the international guidelines as well as the decision of Registration Board i.e. "*For all type of drug products, the value of "Q" should not be less than 75% in any case as per the recommendations of United States Pharmacopoeia (USP) General Chapter <711> Dissolution, Dissolution testing in BP finished products monographs for solid oral dosage forms and The International Pharmacopoeia Ninth Edition, 2019 -Dissolution testing of tablets and capsules"*. As per the submitted data percentage of drug release at 30 minutes was 55.09% in the USFDA recommended	Firm has submitted the reply, in which it is stated that "The dissolution time for pazonix 200mg tablet has been selected 60 minutes as per the FDA dissolution database. In the database, USP apparatus Type-II and 10,20,30,45 and 50 min has been mentioned for profiling. For the immediate release tablet, we have selected 60 mins as a single time point. Firm has not given any scientific justification for selecting the extreme time point i.e. 60 minutes for dissolution of drug product, while the FDA review document of innovator product reveals that the dissolution criteria should be Q= at 30 minutes using the following conditions. Apparatus: USP Apparatus 2 Volume: 900 mL Medium: 50 mM sodium acetate buffer, pH 4.5, containing 0.75% SDS Agitation: Paddle speed of 75 rpm. Analysis: UV at 270 nm with a background correction at 400 nm. Temperature: 37°C.

	release media. Justify, how your formulation can be considered equivalent to the innovator product which shows release more than Q+5% in 30 minutes.	
3	• Justify how the results of all quality tests for every batch in stability studies are same at all time points. • Justification is required regarding the out of specification assay results i.e. 46.5mg content of pazopanib per tablet at 6-month time interval during the accelerated stability studies of batch no. 3860003 and 3860004.	Firm has not provided any justification regarding these queries, instead submit the stability data of commercial batches. (batch no. 3860005,3860006,3860007)
4	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Firm has submitted the Batch Manufacturing Record of batch no. 3860002, 3860003 and 3860004.
5	Firm has submitted the differential fee of Rs. 50,000 vide Challan no.78134245317 dated 22-08-2022 for finished import drug product, as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	

Decision: Deferred for Scientific justification regarding difference in dissolution limits in terms of %age released and time point from that recommended by the US FDA for innovator product .

Previously Deferred Cases of Form 5-F:

522.	Name, Address of Applicant / Marketing Authorization Holder	M/s Bio-Next Pharmaceuticals Plot No. 50, Street No. S-10, RCCI Industrial Estate, Rawat Islamabad- Pakistan
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt). Ltd Plot No. 145industrial Triangle Kahuta road Islamabad.
	Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. dated 10/03/2021
	Details of fee submitted	PKR 50,000/-: dated 23/04/2020
	The proposed proprietary name / brand name	Nextcraft 1MIU Injection IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium….1MIU
	Pharmaceutical form of applied drug	Glass vial filled with almost white to off-white coloured Lyophilized Powder.
	Pharmacotherapeutic Group of (API)	Antibiotics

	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Colistim Injection by Pharmasol (Pvt) Ltd
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conduct 23-4-2019, valid upto 22-4-2022.
	Name and address of API manufacturer.	Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 6oC ± 2 oC, RH for 48 months Accelerated: 25oC ± 2 o C/60% ± 5%RH for 6 months Batches:(CLS0219006, CLS0219008, CLS0219009)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Colistim Injection by Pharmasol (Pvt) Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		
Manufacturer of API		Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane.
API Lot No.		A1680997, A1681004, A1600290
Description of Pack (Container closure system)		Glass vial
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period		Real time: 24 months Accelerated: 6 months
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 ,9,12,18,24(Months)

Batch No.		L-159	L-182	L-199
Batch Size		18200 Vials	28000 Vials	30000vials
Manufacturing Date		05-2018	09-2018	12-2018
Date of Initiation		29-05-18	03-10-18	21-12-2018
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Empaglif 10mg & 25mg tablet in 296th meeting (Bio-Labs (Pvt). Ltd, Islamabad).		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (NEW-WHO GMP/CERT/KD/74238/2018/11/24897) issued by Maharashtra food and drug administration dated 11-09-2018. The certificate is valid till 10-09-2021.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Colistimethate sodium 5Kg from Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane. The license was issued on 14-02-2020. • Firm has submitted copy of commercial invoice dated 14-02-2020 specifying import of Colistimethate sodium 5Kg. The invoice is signed by AD (I&E) DRAP.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches including COA and summary data sheets.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The product specifications of colistimethate sodium injection based on USP and there is no application of HPLC in testing method because the assay method based on microbial assay therefore compliance record of HPLC is not applicable here.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Remarks OF Evaluator:

• Provide detailed analytical procedures for the testing of drug substance by the drug product manufacturer. • Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Firm submitted the analytical method verification studies. Verification has been done on assay procedure which is also not as per the USP.
Justify 90.1mg filled weight of colistimethate sodium per vial against the labelled claim of colistin activity as per the USP monograph of "colistimethate for injection".	Nominal potency of colistimethate sodium used for calculation of filled weight is not correct, according to the innovator product of Colistimethate sodium 1MIU the nominal potency of the drug substance =12,500 IU/mg. So, using of 90.1 filled weight is still not scientifically rationale.
All quality test as per USP monograph has not been performed while establishing the pharmaceutical equivalence against the reference product. Provide results of all quality test of applied and reference product as per USP to establish pharmaceutical equivalence.	Test for uniformity of dosage unit, loss on drying, and free colistin under Colistimethate Sodium are not performed while establishing pharmaceutical equivalence with the reference product, while these tests are included in the USP monograph of colistimethate sodium injection.
Details of type and quantity of diluents used for reconstitution for of applied product is required.	According to the submitted information, to reconstitute the injection, use 3ml 0.9% sodium chloride solution.

	While the international reference product including the innovator, use the range of 7ml-10ml of water for injection or 0.9% sodium chloride for reconstitution of colistimethate injection.
Provide detailed analytical procedures used to evaluate the quality of drug product by the Manufacturer M/s. Bio-Lab Pvt. Ltd.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Further, the test for uniformity of dosage unit, loss on drying, heavy metals, and free colistin under Colistimethate Sodium are not included in finished product specification, since these tests are included in the USP monograph.
According to the filled BMR batch size of Batch L-159, L-199 and L-182 is 11090vials,11,000 vials and 11050 vials respectively. While according to the stability data sheet batch size of all three batches are L-159 18,200 vials, L-199 30,000 vials and L-182 28,000 vials. Justification is required regarding the disparity observed in the batch sizes of the same batch.	Firm submitted the reply that "Batch sizes mentioned on stability was written mistakenly. Please consider BMR batch sizes (11,111 packs) as valid batch size. Correct stability data has been submitted.

Decision of 316th meeting of Registration Board:
Deferred for the submission of following:

- Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
- Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
- For further deliberation regarding the label claim of Colistimethate sodium in line with the product approved in reference regulatory agencies and pharmacopeia.

Response of the Firm:
Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
Firm has submitted the revised microbial assay method which is again not in accordance with USP general chapter microbial assay <81> in terms of analysis and calculations.
Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
Firm has submitted the calculation, according to which quantity of 87.144mg of colistimethate injection has been filled per vial after adjustment of water content and sodium factor. Further, firm set the internal fill weight ±4% i.e. 83.65mg to 90.62 mg and fill weight set at 90mg/vial.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
Firm has submitted revised pharmaceutical equivalence report in which only test for uniformity of dosage unit has been added but test for loss on drying and free colistin still not been included.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
Firm has submitted the revised stability data and COA of relevant stability batches, in which test for loss on drying and free colistin was still not included neither any scientific justification has been submitted.

Decision: Registration Board deferred the case for following points:

- **submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.**
- **Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.**

• **Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.** • **Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.**		
523.	Name, Address of Applicant / Marketing Authorization Holder	M/s. Benson Pharmaceuticals Plot #3 Mai Road National Industrial Zone RCCI Rawat Pakistan.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt). Ltd Plot No. 145industrial Triangle Kahuta road Islamabad.
	Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10322 dated 02/04/2021
	Details of fee submitted	PKR 50,000/-: vide slip no. 1913592 dated 08/03/2021
	The proposed proprietary name / brand name	Coliben 1MIU Injection IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium……..…….1MIU
	Pharmaceutical form of applied drug	Glass vial filled with almost white to off-white colored Lyophilized Powder.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Colistim Injection by Pharmasol (Pvt) Ltd
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conduct 23-4-2019, valid upto 22-4-2022.
	Name and address of API manufacturer.	Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 6°C ± 2 °C, RH for 48 months Accelerated: 25°C ± 2 °C/60% ± 5%RH for 6 months Batches:(CLS0219006, CLS0219008, CLS0219009)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Colistim Injection by Pharmasol (Pvt) Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane.		
API Lot No.	A1680997, A1681004, A1600290		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 ,9,12,18,24(Months)		
Batch No.	L-159	L-182	L-199
Batch Size	18200 Vials	28000 Vials	30000vials
Manufacturing Date	05-2018	09-2018	12-2018
Date of Initiation	29-05-18	03-10-18	21-12-2018
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Empaglif 10mg & 25mg tablet in 296th meeting (Bio-Labs (Pvt). Ltd, Islamabad).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (NEW-WHO GMP/CERT/KD/74238/2018/11/24897) issued by Maharashtra food and drug administration dated 11-09-2018.The certificate is valid till 10-09-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Colistimethate sodium 5Kg from Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane. The license was issued on 14-02-2020.

		• Firm has submitted copy of commercial invoice dated 14-02-2020 specifying import of Colistimethate sodium 5Kg. The invoice is signed by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches including COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

• Provide detailed analytical procedures for the testing of drug substance by the drug product manufacturer. • Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Firm submitted the analytical method verification studies. Verification has been done on assay procedure which is also not as per the USP.
Justify 90.1mg filled weight of colistimethate sodium per vial against the labelled claim of colistin activity as per the USP monograph of "colistimethate for injection".	Nominal potency of colistimethate sodium used for calculation of filled weight is not correct, according to the innovator product of Colistimethate sodium 1MIU the nominal potency of the drug substance =12,500 IU/mg. So, using of 90.1 filled weight is still not scientifically rationale.
All quality test as per USP monograph has not been performed while establishing the pharmaceutical equivalence against the reference product. Provide results of all quality test of applied and reference product as per USP to establish pharmaceutical equivalence.	Test for uniformity of dosage unit, loss on drying, and free colistin under Colistimethate Sodium are not performed while establishing pharmaceutical equivalence with the reference product, while these tests are included in the USP monograph of colistimethate sodium injection.
Details of type and quantity of diluents used for reconstitution for of applied product is required.	According to the submitted information, to reconstitute the injection, use 3ml 0.9% sodium chloride solution. While the international reference product including the innovator, use the range of 7ml-10ml of water for injection or 0.9% sodium chloride for reconstitution of colistimethate injection.
Provide detailed analytical procedures used to evaluate the quality of drug product by the Manufacturer M/s. Bio-Lab Pvt. Ltd.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Further, the test for uniformity of dosage unit, loss on drying, heavy metals, and free colistin under Colistimethate Sodium are not included in finished product specification, since these tests are included in the USP monograph.
According to the filled BMR batch size of Batch L-159, L-199 and L-182 is 11090vials,11,000 vials and 11050 vials respectively. While according to the stability data sheet batch size of all three batches are L-159 18,200 vials, L-199 30,000 vials and L-182 28,000 vials. Justification is required regarding the disparity observed in the batch sizes of the same batch.	Firm submitted the reply that "Batch sizes mentioned on stability was written mistakenly. Please consider BMR batch sizes (11,111 packs) as valid batch size. Correct stability data has been submitted.

Decision of 316th meeting of Registration Board:
Deferred for the submission of following:

- Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
- Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
- For further deliberation regarding the label claim of Colistimethate sodium in line with the product approved in reference regulatory agencies and pharmacopeia.

Response of the Firm:
Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
Firm has submitted the revised microbial assay method which is again not in accordance with USP general chapter microbial assay <81> in terms of analysis and calculations.
Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
Firm has submitted the calculation, according to which quantity of 87.144mg of colistimethate injection has been filled per vial after adjustment of water content and sodium factor. Further, firm set the internal fill weight ±4% i.e. 83.65mg to 90.62 mg and fill weight set at 90mg/vial.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
Firm has submitted revised pharmaceutical equivalence report in which only test for uniformity of dosage unit has been added but test for loss on drying and free colistin still not been included.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
Firm has submitted the revised stability data and COA of relevant stability batches, in which test for loss on drying and free colistin was still not included neither any scientific justification has been submitted.

Decision: Registration Board deferred the case for following points:

- **submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.**
- **Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.**
- **Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.**
- **Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.**

524.	Name, address of Applicant / Marketing Authorization Holder	M/s Novartana Pharmaceuticals (Pvt). Ltd 87-B Plot of Sundar Industrial Area, Raiwind Road, Lahore Pakistan.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt). Ltd Plot No. 145industrial Triangle Kahuta road Islamabad.
	Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No.10322 dated 02/04/2021
	Details of fee submitted	PKR 50,000/-: vide slip no. 1913592 dated 08/03/2021
	The proposed proprietary name / brand name	ColiNova 1MIU Injection IV

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium…….…….1MIU
	Pharmaceutical form of applied drug	Glass vial filled with almost white to off-white colored Lyophilized Powder.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Colistim Injection 80mg by Pharmasol (Pvt) Ltd. Reg.no. 089922
	GMP status of the Finished product manufacturer	GMP certificate no. F.3-19/2019-Addl.Dir. (QA&LT-I) issued based upon inspection conducted on 23-04-2019, valid up to 22-04-2022.
	Section Approval Status	Firm has Lyophilized vial section as per the GMP certificate issued based upon inspection conducted on 23-04-2019, valid up to 22-04-2022.
	Name and address of API manufacturer.	DMF Holder Address: Mac Chem Products (India) Pvt. Ltd. 304, Town Centre, Andheri-Kurla Road, Andheri East Mumbai Manufacturing and Testing Facilities: Mac-Chem Products (India)Pvt.Ltd N-211/2/10, MIDC, Boisar District –Thane. Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(CLS0219006, CLS0219008, CLS0219009)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence Biological Assay for their product against the comparator i.e. Colistim Injection 80mg by Pharmasol (Pvt) Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA				
Manufacturer of API		Mac-Chem Products (India)Pvt.LtdN-211/2/10, MIDC, Boisar District –Thane.		
API Lot No.		A1680997, A1681004, A1600290		
Description of Pack (Container closure system)		Glass vial		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 24 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 ,9,12,18,24(Months)		
Batch No.		L-159	L-182	L-199
Batch Size		18200 Vials	28000 Vials	30000vials
Manufacturing Date		05-2018	09-2018	12-2018
Date of Initiation		29-05-18	03-10-18	21-12-2018
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Empaglif 10mg & 25mg tablet in 296th meeting (Bio-Labs (Pvt). Ltd, Islamabad).		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (NEW-WHO GMP/CERT/KD/74238/2018/11/24897) issued by Maharashtra food and drug administration dated 11-09-2018. The certificate is valid till 10-09-2021.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Colistimethate sodium 5Kg from Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc,Boisar District –Thane. The license was issued on 14-02-2020. • Firm has submitted copy of commercial invoice dated 14-02-2020 specifying import of Colistimethate sodium 5Kg. The invoice is signed by AD (I&E) DRAP.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches including COA and summary data sheets.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Remarks OF Evaluator:

• Provide detailed analytical procedures for the testing of drug substance by the drug product manufacturer. • Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Firm submitted the analytical method verification studies.

	Verification has been done on assay procedure which is also not as per the USP.
Justify 90.1mg filled weight of colistimethate sodium per vial against the labelled claim of colistin activity as per the USP monograph of "colistimethate for injection".	Nominal potency of colistimethate sodium used for calculation of filled weight is not correct, according to the innovator product of Colistimethate sodium 1MIU the nominal potency of the drug substance =12,500 IU/mg. So, using of 90.1 filled weight is still not scientifically rationale.
All quality test as per USP monograph has not been performed while establishing the pharmaceutical equivalence against the reference product. Provide results of all quality test of applied and reference product as per USP to establish pharmaceutical equivalence.	Test for uniformity of dosage unit, loss on drying, and free colistin under Colistimethate Sodium are not performed while establishing pharmaceutical equivalence with the reference product, while these tests are included in the USP monograph of colistimethate sodium injection.
Details of type and quantity of diluents used for reconstitution for of applied product is required.	According to the submitted information, to reconstitute the injection, use 3ml 0.9% sodium chloride solution. While the international reference product including the innovator, use the range of 7ml-10ml of water for injection or 0.9% sodium chloride for reconstitution of colistimethate injection.
Provide detailed analytical procedures used to evaluate the quality of drug product by the Manufacturer M/s. Bio-Lab Pvt. Ltd.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Further, the test for uniformity of dosage unit, loss on drying, heavy metals, and free colistin under Colistimethate Sodium are not included in finished product specification, since these tests are included in the USP monograph.
According to the filled BMR batch size of Batch L-159, L-199 and L-182 is 11090 vials, 11,000 vials and 11050 vials respectively. While according to the stability data sheet batch size of all three batches are L-159 18,200 vials, L-199 30,000 vials and L-182 28,000 vials. Justification is required regarding the disparity observed in the batch sizes of the same batch.	Firm submitted the reply that "Batch sizes mentioned on stability was written mistakenly. Please consider BMR batch sizes (11,111 packs) as valid batch size. Correct stability data has been submitted.

Decision of 316th meeting of Registration Board:
Deferred for the submission of following:

- Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
- Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
- For further deliberation regarding the label claim of Colistimethate sodium in line with the product approved in reference regulatory agencies and pharmacopeia.

Response of the Firm:
Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
Firm has submitted the revised microbial assay method which is again not in accordance with USP general chapter microbial assay <81> in terms of analysis and calculations.
Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
Firm has submitted the calculation, according to which quantity of 87.144mg of colistimethate injection has been filled per vial after adjustment of water content and sodium factor. Further, firm set the internal fill weight ±4% i.e. 83.65mg to 90.62 mg and fill weight set at 90mg/vial.

Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies. Firm has submitted revised pharmaceutical equivalence report in which only test for uniformity of dosage unit has been added but test for loss on drying and free colistin still not been included. Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies. Firm has submitted the revised stability data and COA of relevant stability batches, in which test for loss on drying and free colistin was still not included neither any scientific justification has been submitted.
Decision: Registration Board deferred the case for following points: • **submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.** • **Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.** • **Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.** • **Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.**

525. <u>Previously Deferred case of Finished Import Product of Form5-F</u>

Name, address of Applicant / Importer	M/s. Martin Dow Limited Plot no. 37, Sector 19, Korangi Industrial Area, Karachi.
Details of Drug Sale License of importer	License No: 521 Address: Plot No.37 Sector 19 K.I.A. Karachi Godown Addresses:1. 1st Floor Plot no.211 Sector 23 K.I.A. Karachi Plot no. 302 Sector 16 K.I.A. Karachi Validity: 16/06/2022 Status: by way of wholesale
Name and address of marketing authorization holder (abroad)	M/s. Duopharma (M) SDN.BHD. Lot 2599, JALAN SERULING 59 KAWASAN 3, TAMAN KLANG JAYA 41200 KLANG, Selangor, Malaysia.
Name, address of manufacturer(s)	M/s. Duopharma HAPI Sdn. Bhd. No.2, Jalan Saudagar U1/16, Zon Perindustrian HICOM Glenmarie, Seksyen U1,40150 Shah Alam, Selangor, Malaysia.
Name of exporting country	Malaysia
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized & marketed COPP (Certificate# 0095/2021) issued by Pharmaceutical Services Division Ministry of Health Malaysia. • Firm has submitted Legalized copy of GMP certificate (Certificate No.1330/19) issued by Competent authority of "Malaysia" in the name of Duopharma HAPI Sdn. Bhd. No.2, Jalan Saudagar U1/16, Zon Perindustrian HICOM Glenmarie, Seksyen U1,40150 Shah Alam, Selangor, Malaysia., valid for 3 years from the date of inspection conducted on 16-17 July 2019.	
Details of letter of authorization / sole agency agreement • "Letter of Authorization" submitted issued by M/s. Duopharma HAPI Sdn. Bhd. No.2, Jalan Saudagar U1/16, Zon Perindustrian HICOM Glenmarie, Seksyen U1,40150 Shah Alam, Selangor, Malaysia. In the name of M/s Martin Dow for the applied product of "Lebreta 2.5mg (Letrozole Tablets)"	
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No.15628 dated 04-06-2021
Details of fee submitted	Rs.50,000/- dated 03-06-2021 slip no. 73776950099
The proposed proprietary name / brand name	Lebreta 2.5mg (Letrozole Tablets)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains 2.5mg of letrozole
Pharmaceutical form of applied drug	Film-coated tablets
Pharmacotherapeutic Group of (API)	Anti-neoplastic agents, ATC code: L02BG04
Reference to Finished product specifications	USP
Proposed Pack size	30's
Proposed unit price	As per DPC
The status in reference regulatory authorities	FDA approved
For generic drugs (me-too status)	Femara Tablet 2.5mg of M/s. Novartis (Pakistan) Limited (Reg.no.021129)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Name, address of drug substance manufacturer	M/s. Natco Pharma Limited, Chemical Division, Mekaguda Village, Nandigama Mandal, Rangareddy District Telangana, India (L.Dis.No.758/E/(k)/TS/2018 dated 14-02-2018)
Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability studies has been performed and submitted by the firm.
Module-III Drug Product:	All the relevant details are submitted by the firm.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed pharmaceutical equivalence studies and comparative dissolution with the innovator product Femara tablet.
Analytical method validation/verification of product	Analytical method validation studies for drug product has been performed.
Container closure system of the drug product	Blisters
Stability study data of drug product, shelf life and storage conditions	Stability studies has been performed and submitted by the firm. Real time stability studies have been conducted at 30°C/75 % RH. Batch Number — Status 20181101PB — Completed till the claimed shelf life i.e.2years

	20191201 12month data has been submitted 20200201 12month data has been submitted Accelerated stability studies is conducted at 40°C±2°C and 75%±5% RH for 6 months. Shelf life: 24month

Remarks of Evaluator:

Sr.#	Section#	Observations	Firm's response
1.	3.2. S.4	Justify, the verification studies of the drug substance without performing test for accuracy parameter.	The methods for drug substance were adopted from the USP40 Monograph. It is considered as Method Verification (Compendial Method). Based on USP General Chapter <1226>, the verification requirements/parameters that are considered to be appropriate for verification of the particular procedure need to be evaluated during the method verification. The Malaysia, National Pharmaceutical Regulatory Agency (NPRA), formerly known as the National Pharmaceutical Control Bureau (NPCB) had come out with an Analytical Method Validation Guideline stating that the Accuracy parameter and the reliability of these methods are not required to be validated for monograph method (compendial method), but merely verify the methods suitability (System Suitability Testing) under actual conditions of use. Hence, the method verification (compendial method) was not conducted. The accuracy parameters were only performed when validating non-compendial methods. According to the USP General Chapter <1226>*Verification should include an assessment of elements such as the effect of the matrix on the recovery of impurities and drug substances from the drug product matrix, as well as the suitability of chromatographic conditions and* *column, the appropriateness of detector signal response, etc. Recovery studies. This statement indicates that accuracy parameter is the part of verification studies.*
2.	P.2.2.1	Product development studies performed by sending unit i.e. Natco Pharma revealed that after optimization of formulation, the cumulative % of drug release is not less than 85% within 15min as evident from the comparative dissolution profile of exhibit batch of Natco Pharma with RLD Femara tablet in all 4 mediums with 75rpm.While the Comparative dissolution profile of receiving unit i.e. DUOPHARMA HAPI SDN.BHD.Malaysia with the product of Natco pharma shows that average % release of both products are less than	Duopharma HAPI also conducted CDP against Femara 2.5mg (Letrozole) (Brand Leader) and Letrozole Tablets USP, 2.5mg (Natco Pharma). The batch number as below: 1. Duopharma HAPI: 20200201 2. Brand Leader: SUH88 3. Natco Pharma: 410120 From the report (DH.QC.R.CD.002.AD.01), the % dissolution for Natco Pharma at 15 mins for all 4 mediums were also less than 85%. The CDP was proven similar by F2 calculation.

		85% in 15minutes. Justify, the significant variation observed in cumulative % of drug release. • Provide Pharmaceutical Equivalence report between Lebreta tablet and innovator product since the submitted report was between letrozole tablet of Natco Pharma and femara tablet (innovator product).	The Bioequivalent Study (BE) was also conducted for Duopharma HAPI product (Batch No.: 20200201) against the Brand Leader (Batch No.: SUH88) and the BE study passed. Therefore, it justifies the variation of dissolution of < 85% at 15 mins timepoint is not significant.
3.	3.2.P.5.3	Justify, why the accuracy parameter has been performed only at 100% concentration, since the ICH guideline for validation of analytical procedure specify that "*Accuracy should be assessed using a minimum of 9 determinations over a minimum of 3 concentration levels covering the specified range (e.g., 3 concentrations/3 replicates each of the total analytical procedure).*"	For Finished Product, the approach of the method was by the Method Transfer (Comparative Testing Approach) as the Duopharma HAPI Sdn Bhd is a Technology Transfer Plant. This Method Transfer is governed under USP General Chapter <1224> Transfer of Analytical Procedures. Based on the guideline, the method transfer is a documented process that qualifies a laboratory (the Receiving Unit) to use an analytical test procedure that originated in another laboratory (the Transferring Unit) to ensure that the Receiving Unit has the procedural knowledge and ability to perform the transferred analytical procedure as intended. The method validation must be completed prior to the Method Transfer activity. For these methods of the Finished Product, the method validations were conducted by the Transferring Unit. The accuracy parameter was conducted by Transferring Unit based on the ICH Guideline and the USP General Chapter <1225> Validation of Compendial Procedures. The details are as below: 1. Assay: 20%, 100%, 200% and 320% concentration level where each concentration had triplicate samples (total = 12 samples) 2. Related Compounds: LOQ%, 50%, 100% and 200% concentration level where each concentration had triplicate samples (total = 12 samples) 3. Dissolution: 40%, 100% and 160% concentration level where each concentration had triplicate samples (total = 9 samples) During the Method Transfer activity, the accuracy parameter was included at only 100% concentration to verify the method accuracy at the actual concentration of testing.
4.	3.2.P.8.2	Justify the out of specification result of dissolution at 18th month time point i.e. 79% since the acceptance criteria of dissolution is NLT 80% (Q) in 30 minutes.	The dissolution for 18th month timepoint for 20181101PB was still passed within the acceptance criteria at Stage 2. Based on USP General Chapter <711>.The first 6 tablets (Stage 1) obtained below Q (Q=80%), which was 79% (minimum result), then Stage 2 was proceeded. Another 6 tablets were analyzed. Based on 12 tablets (Stage 1 + Stage 2), the average reading obtained was 88% which is ≥ Q (Q=80%) and no tablet was < Q-15% (Q-15% = 65%).

			Therefore, the dissolution at 18th month for 20181101PB passed within the acceptance criteria at Stage 2. Moreover, the additional timepoints of the following batches have been completed.
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) of drug product of batch no.20181101PB, since the stability studies data of the said batch has been submitted in Module 3 section 3.2. P.8.	Firm has provided the BMR of batch no. 20181101PB.

Decision of 316th meeting of Registration Board:
Deferred for submission of following:

- Pharmaceutical equivalence studies data of Lebreta 2.5mg tablet manufactured by M/s. Duopharma HAPI Sdn. Bhd. No.2, Jalan Saudagar U1/16, Zon Perindustrian HICOM Glenmarie, Seksyen U1,40150 Shah Alam, Selangor, Malaysia against the innovator product/reference product, since the submitted pharmaceutical equivalence data was between letrozole tablet of M/s Natco Pharma and Femara tablet (innovator product).
- Analytical verification studies of drug product in accordance with relevant guidelines.

Response of the Firm:
Pharmaceutical equivalence studies data of Lebreta 2.5mg tablet manufactured by M/s. Duopharma HAPI Sdn. Bhd. No.2, Jalan Saudagar U1/16, Zon Perindustrian HICOM Glenmarie, Seksyen U1,40150 Shah Alam, Selangor, Malaysia against the innovator product/reference product, since the submitted pharmaceutical equivalence data was between letrozole tablet of M/s Natco Pharma and Femara tablet (innovator product).
Firm has submitted pharmaceutical equivalence data, which incudes only the result of content of active ingredient of test product (Letronat 2.5 mg Tablet of M/s. Duopharma HAPI Sdn. Bhd., Malaysis and reference product (Femara 2.5mg Tablet manufactured by Novartis Pharma Stein, Switzerland).
Further, firm submitted the bioequivalence study report of Letronat 2.5 mg Tablet of M/s. Duopharma HAPI Sdn. Bhd., Malaysia with Femara 2.5mg Tablet manufactured by Novartis Pharma Stein, Switzerland.

Analytical verification studies of drug product in accordance with relevant guidelines.

- Firm submitted the reply in which it is stated that "the assay method was validated by Natco Pharma Limited and successfully transferred from Natco Pharma Limited to Duopharma HAPI via method transfer based on guidance from USP General Chapter <1224>". There are several approaches to the method transfer, for this method transfer, comparative testing approach has been adopted.
- Duopharma HAPI has performed the accuracy parameter at 100% concentration and Natco Pharma has performed it on 4 different concentrations and since Duopharma was comparing all the results with Natco Pharma Limited as the Method Transferrer. There is no requirement to test accuracy at 3 different concentrations.

Comparative testing approach in USP General Chapter <1224> stated that "Comparative testing requires the analysis of a predetermined number of samples of the same lot by both the sending and the receiving units. Other approaches may be valid, e.g., if the receiving unit meets a predetermined acceptance criterion for the recovery of an impurity in a spiked product. Such analysis is based on a preapproved transfer protocol that stipulates the details of the procedure, the samples that will be used, and the predetermined acceptance criteria, including acceptable variability. Meeting the predetermined acceptance criteria is necessary to assure that the receiving unit is qualified to run the procedure".
Firm has submitted the analytical method transfer report in accordance with the guidance of abovesaid USP General chapter.

Decision: Approved with USP specifications as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

Deferred Cases of Form-5:

526.	Name and address of manufacturer / Applicant	M/s. Innvotek Pharmaceuticals, Plot no.35, Industrial Triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bromycin-D Eye Ointment
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No. dated 15-03-2018 Rs. 8,000/- (photocopy)

		With the statement that due to late submission of differential fee 12,000/- there product was not discussed in any Registration Board so to avoid further delay they withdraw from the fee of rs. 8,000/- i.e. earlier submitted in April, 2005, Dy.no. 570.Now, they resubmitted Rs. 8,000/- and apply for the registration of product. Differential fee (photocopy) of Rs.12,000/- submitted on 05/11/2015 Dy.No.1950 (verified from R&I)
	Composition	Each gram contains: Tobramycin….3mg (0.3% w/w) Dexamethasone…1mg (0.1%w/w)
	Pharmacological Group	Aminoglycoside antibiotic/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	USFDA Approved (Tobradex Ophthalmic Ointment tobramycin 0.3% (3 mg) and dexamethasone 0.1% (1 mg).
	Me-too Status	Obradex Eye Ointment of M/s. Vega Pharmaceuticals, Lahore (Reg.no.067753)
	GMP Status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I). Eye ointment & Cream (sterile) General section is mentioned in the said certificate.
	Remarks of the Evaluator.	Evidence of availability of separate steroidal dispensing booth is required.
	Decision of 312th meeting of Registration Board	Deferred for clarification regarding status of application.
	Response of the Firm	Firm submitted the clarification in response of decision of Registration Board in which it is stated that "It was mistakenly mentioned in the covering letter of year 2018 which was submitted with fee of Rs.8,000/-,regarding withdrawal of fee of Rs.8,000/- which was deposited initially in 2005 along with Form-5.
	Decision: Approved. • **Frim shall submit evidence of availability of separate dispensing booth for steroidal drug substance.** • **Firm shall also submit fresh fee of Rs. 30,000/-, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
527.	Name and address of manufacturer / Applicant	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	M. Brozine Injection
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No. dated 16/06/2011 Rs 8,000/- (photocopy fee challan) Dy. No. dated 16/12/2015 Rs. 12,000/- (photocopy fee challan) (Not verified from R&I)
	Composition	Each ml contains: - Promethazine HCl …… 25mg
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10 x 2ml's
	Approval Status of Product in Reference Regulatory Authorities	Phenergan Injection 25mg/ml Oral by M/s Aventis Pharma Limited, trading as Sanofi, Emc Approved.
	Me-too Status	Phenerzine Injection by EPOCH Pharma (Reg#050476)
	GMP Status	Panel inspection for renewal of DML conducted on 15-12-2020,16-12-2020,26-01-2021 concluded with the following remarks:

		"The panel recommends the renewal of Drug Manufacturing License to M/s. Jawa Pharmaceuticals (Pvt.) Ltd., Lahore by way of formulation"
	Remarks of the Evaluator.	
	Decision of 308th meeting of Registration Board	Deferred for verification of receiving of Registration application from R&I section, DRAP.
	Remarks of the Evaluator	R&I Section of DRAP verified the receiving of fee of Rs.8,000 vide Dy.no. 2283 dated 16-06-2011 and Differential fee of RS.12,000/- received vide Dy.no. 261 dated 16-12-2015.
	Decision: Approved.	

A. Registration applications Veterinary (New): -

528.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	THAIBONDOL Suspension	
	Composition	Each ml Contains: Thiabendazole……133.00 mg	
	Diary No. Date of R & I & fee	Dy. No 12165 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anthelmintic	
	Type of Form	Form - 5	
	Finished product Specification	USP	
	Pack size & Demanded Price	50ml,100ml,150ml,250ml,500ml,1000ml,2.5L	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Thiabendazole oral liquid,058716, Selmore Pharmaceuticals (Pvt) ltd Lahore	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Form 5 prescribed title page dully signed is not provided along with preregistration variation fee challan. • Composition of Active Ingredients per ML is required.	Firm has submitted fee challan No.1856802411 dated 16-06-2022 of 30000/= along with Composition of API /ml, master formulation, manufacturing method, finished product testing method and signed title page.
	Decision: Approved		
529.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	

	Brand Name + Dosage Form + Strength	BIO-AMOXYLLIN Water Soluble Powder	
	Composition	Each 100 gm Contains: Amoxicillin Trihydrate Equivalent to Amoxicillin Base……70 mg	
	Diary No. Date of R & I & fee	Dy. No 12316 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	B.P (Vet)	
	Pack size & Demanded Price	100 g,250 g,500g,1 kg,2 kg,2.5kg,3kg,5,kg.As per SRO	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	PRIMOX 70% WATER SOLUBLE POWDER, 074032, M/s prix pharmaceutical (Pvt) ltd., plot # 5 pharma city, 30-km Multan Road, Lahore.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Form 5 prescribed title page dully signed is not provided along with preregistration variation fee challan.	Firm has submitted fee challan No.545022401 dated 16-06-2022 of 7500/= along with master formulation, manufacturing method, finished product testing method and signed title page.
	Decision: Approved		
530.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	TYLAX Injection	
	Composition	Each ml Contains: Tylosin Tartrate eq to Tylosin ……...200 mg	
	Diary No. Date of R & I & fee	Dy. No 12166 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	USP	

	Pack size & Demanded Price	100 ml glass vial type II, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Positive 200 Injection., 063504, M/s Cherished Pharmaceuticals (Private) Limited, Lahore	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Pre-registration variation fee challan.	Firm has submitted fee challan No.475433920 dated 16-06-2022 of 7500/= along with master formulation, manufacturing method, finished product testing method, Packing/closure and signed title page.
	Decision: Approved		
531.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	SELMEC Injection	
	Composition	Ivermectin……20 mg	
	Diary No. Date of R & I & fee	Dy. No 12162 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anthelmintic	
	Type of Form	Form - 5	
	Finished product Specification	USP	
	Pack size & Demanded Price	250 ml,t ype II glass vial.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	FARMEC-2 INJECTION, 063722, LEADS PHARMA (PVT) LTD., ISLAMABAD.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab	

		(pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided.	Firm has submitted fee challan No.21841031354 dated 16-06-2022 of 30000/= along with composition of API/ml (**Each ml Contains Ivermectin…20mg),** master formulation, manufacturing method, finished product testing method, Packing/closure and signed title page.
	Decision: Approved		
532.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	DOXYRAL Powder	
	Composition	Each gram Contains: Doxycycline Hyclate 923.32 mg equivalent to Doxycycline base…….800 mg	
	Diary No. Date of R & I & fee	Dy. No 12311 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Tricyclic Antibiotics.	
	Type of Form	Form - 5	
	Finished product Specification	Innovator Specification.	
	Pack size & Demanded Price	100 gm, 500 gm, 1000 gm, 2000 gm, 5000 gm.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	DOXYRAL 80% WATER SOLUBLE POWDER FOR ORAL ROUTE, 082504, "M/S. ORIENT ANIMAL HEALTH (PVT.) LIMITED, KARACHI	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin)	

		Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Form 5 prescribed title page dully signed is not provided. • Pack Size, container and closure is not provided.	Firm has submitted fee challan No.928002485967 dated 16-06-2022 of 30000/= along with revise composition of API, master formulation, manufacturing method, finished product testing method, Packing/closure and signed title page.
	Decision: Approved.		
533.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	CLIMISOL Injection	
	Composition	Levamisol……75 mg Closental……...50 mg	
	Diary No. Date of R & I & fee	Dy. No 12163 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anthelmintic	
	Type of Form	Form - 5	
	Finished product Specification	Innovator's	
	Pack size & Demanded Price	100 ml,	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	CLOMISOL Injection, 049641, SELMORE PHARMACEUTICALS, LAHORE.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications	Firm has submitted fee challan No.90832036251 dated 16-06-2022 of 30000/= and submiited revised dosage form and strength of APIs as under:

		mentioning assay of finished products. • Fee Challan mentioned dosage form as drench where as Form -5 mentioned as Injection. • Firm did not mention per ml composition. • Pack Size, container and closure is not provided. • Evidence of me-too status of product already registered in Pakistan.	**"CLOMISOL Injection Each ml Contains: Levamiol as Hcl...75 mg Closental……50 mg".** Firm has also submitted revised master formulation, Pack size, Finished product specification and signed Form-5.
	Decision: Approved with Innovator Specification with following label claim; "CLOMISOL Injection 100 ml" Each ml Contains: Levamiol as Hcl.....75 mg Closental……..50 mg".		
534.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	PENISEL-40 mg Injection (Dry Powder)	
	Composition	Each ml Contains: Procaine Penicillin G……...3000000 IU Benzathine Penicillin G……...1000000 IU	
	Diary No. Date of R & I & fee	Dy. No 12164 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Board Spectrum Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	innovator	
	Pack size & Demanded Price	Dry Powder Glass vial of type -II.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Penisel-40 Dry Powder Injection, 080956, Selmore Pharmaceuticals ,Lahore.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master formulation with Complete Outline of manufacturing method is required.	• Firm has submitted fee challan No.1902686189 dated 16-06-2022 of 30000/= and submitted

		• Complete finished good testing specifications mentioning assay of finished products. • Form-5 cover letter dully signed by management. • Evidence of me-too status of product registered in Pakistan.	revised dosage form as "Dry Powder Vial "along with revised Form- 5, Manufacturing method, master formulation, Pack size, and finished product specification. The revised composition is as under: **Each Dry Powder Vial Contains:** **Procaine Penicillin…...3000000 IU** **Benzyl penicillin……10,00,000 IU**
	Decision: Approved with innovators specification with following label claim; **"Each Dry Powder Vial Contains:** **Procaine Penicillin…….3000000 IU** **Benzyl penicillin……10,00,000 IU"**		
535.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	UTERICIN Intrauterine Injection	
	Composition	Each syringe of 20 gm Contains: Benzyl Penicillin (As procaine) ……1000000 IU Gentamycin (As Sulaphate) ……...200000 IU	
	Diary No. Date of R & I & fee	Dy. No 12309 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Board Spectrum Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	Not provided	
	Pack size & Demanded Price	Pack Size, Container and closure is not provided.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	UTERICINE INTRAUTERINE INJECTION (prefilled syringe), 027482, VETQUINOL FRANCE, A.B.I. INT FAISALABAD.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	

	Remarks of the Evaluator	• Master formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Form-5 cover letter dully signed by management. • Section approval letter of prefilled syringes from CLB. • Pack Size, container and closure is not provided. • Pre-registration variation fee challan.	
	Decision: Deferred for following Shortcomings: - **1. Master formulation with Complete Outline of manufacturing method is required.** **2. Complete finished good testing specifications mentioning assay of finished products.** **3. Form-5 cover letter dully signed by management.** **4. Section approval letter of prefilled syringes from CLB.** **5. Pack Size, container and closure is not provided.** **6. Pre-registration variation fee challan.**		
536.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	TOCOSEL ORAL SOLUTION	
	Composition	Each 1000 ml contains: Vitamin E…….500 mg Selenium……...120 G	
	Diary No. Date of R & I & fee	Dy. No 123161 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antibacterial	
	Type of Form	Form - 5	
	Finished product Specification	innovator	
	Pack size & Demanded Price	100ml,150ml,250ml,500ml,1L,2.5 L,25L	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Immunosel Oral Solution, 034539, ATTABAK PHARMACEUTICALS, ISLAMABAD,	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications	Firm has submitted fee challan No.0205167051 dated 16-06-2022 of 30000/= along with revised form -5 with revised strength of label claim API as under:

		mentioning assay of finished products. • Form-5 cover letter dully signed by management. • Evidence of me-too status of product registered in Pakistan. • Pack Size, container and closure is not provided.	**Each ml contains:** **Vitamin E….120000 mg** **Selenium as Sodium selenite…...2200 mg**. Firm has also submitted revised Form- 5, Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
537.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	PENCINE W.W Powder	
	Composition	Each Kg powder Contains: Streptomycin……200 gm Penicillin……44 gm	
	Diary No. Date of R & I & fee	Dy. No 12308 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antibiotics	
	Type of Form	Form - 5	
	Finished product Specification	Innovator Specifications	
	Pack size & Demanded Price	250 gm,1000 gm	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	PENCINE W.W. POWDER, 025733, MANHATTAN PHARMA KARACHI.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Form-5 cover letter dully signed by management.	Firm has submitted fee challan No.743165117561 dated 16-06-2022 of 30000/= along with revised form - 5 with revised strength/salt of label claim API as under: **Each Kg contains:** **Streptomycin as sulphate…….200 gm**

		• Pack Size, container and closure is not provided.	**Procaine Penicillin……44gm** Firm has also submitted revised Form- 5, Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision: Approved with innovator specification with following label claim; **"Each Kg contains:** **Streptomycin as sulphate…….200 gm** **Procaine Penicillin……44gm"**		
538.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	BACTICOM Injection	
	Composition	Dimetridazole ……100 mg Tylosin Tartrate…….50 mg Colistin Sulphate……10 mg	
	Diary No. Date of R & I & fee	Dy. No 12156 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Board spectrum antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	Innovator	
	Pack size & Demanded Price	100 ml,Type II glass vial.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Bacticom Injection, 043140, SELMORE PHARMACEUTICALS, LAHORE, LAHORE,	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Form-5 cover letter dully signed by management.	Firm has submitted fee challan No.9552576752 dated 16-06-2022 of 30000/= along with revised form -5 with revised per ml label claim as under: **Each ml contains:** **Dimetridazole …...100 mg** **Tylosin Tartrat….50 mg** **Colistin Sulphate…10 mg** Firm has also submitted revised Form- 5,

		• Pack Size, container and closure is not provided. • Per ml composition is not provided.	Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
539.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	CLIMISOL Drench	
	Composition	Levamisol…….100 mg Closental……...100 mg	
	Diary No. Date of R & I & fee	Dy. No 12160 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anthelmintic	
	Type of Form	Form - 5	
	Finished product Specification	innovator	
	Pack size & Demanded Price	100 ml,250 ml, 500 ml,1000 ml. plastic bottle.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	CLOMISOL DRENCH., 049626, SELMORE PHARMACEUTICALS, LAHORE.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Fee Challan mentioned dosage form as Injection where as Form -5 mentioned as Drench. • Firm did not mention per ml composition. • Pack Size, container and closure is not provided.	• Firm has submitted fee challan No.86060100 dated 16-06-2022 of 30000/= along with revised form -5 with revised per label claim as under: Clomisol Drench 100/100 **Each ml contains:** **Levamisol as Hcl .100 mg** **Closental……100 mg** • Firm has also submitted revised Form- 5, Manufacturing method, master formulation, Pack

		• Evidence of me-too status of product already registered in Pakistan.	size, and finished product specification. • However, the me-too composition of Clomisol Drench is Levamisol Hcl…100mg
	Decision: Approved with innovator specifications with following label claim.; **"Clomisol Drench 100/100** **Each ml contains:** **Levamisol Hcl ……100 mg** **Closental……..…100 mg"**		
540.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	OXYFEN LA Injection	
	Composition	Oxytetracycline……100 mg Ketoprofen……30 mg	
	Diary No. Date of R & I & fee	Dy. No 12153 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	innovator	
	Pack size & Demanded Price	100 ml , type II glass vial.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Oxyfen LA injection, 071091, SELMORE PHARMACEUTICALS, LAHORE.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Firm did not mention per ml composition. • Pack Size, container and closure is not provided.	• Firm has submitted fee challan No.4713859323 dated 16-06-2022 of 30000/= along with revised form -5 with revised per label claim as under: **Each ml contains:** **Oxytetracycline as Dihydrate……200 mg** **Ketoprofen…….30 mg** • Firm has also submitted revised Form- 5, Manufacturing method,

		• Evidence of me-too status of product already registered in Pakistan.	master formulation, Pack size, and finished product specification. • However, Composition of me -too is as under; Oxytetracycline ….200MG Ketoprofen…….30MG
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
541.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	COLIMOXIN FORTE Water-Soluble Powder	
	Composition	Each 100 gm contains: Amoxicillin Trihydrate……20 Gm Colistin Sulphate……80 MIU	
	Diary No. Date of R & I & fee	Dy. No 12313 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	Innovator	
	Pack size & Demanded Price	100gm,250gm,500 gm,1000 gm.Plastic bottle.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Colimoxin Forte Oral Dry Powder, 080961, Selmore Pharmaceuticals (Pvt) Ltd., 36 Km Off. Multan Road Lahore.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Evidence of me-too status of product already registered in Pakistan.	• Firm has submitted fee challan No.379469740 dated 16-06-2022 of 7500/= along with signed form -5 along with Manufacturing method, master formulation, Pack size, and finished product specification.

		• Form-5 cover letter dully signed by management.	
	Decision : Approved with innovator's specifications.		
542.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	NEFCOL ORAL SOLUTION	
	Composition	Each 100 ml contains: Florfenicol…….23 Gm Colistin Sulphate……50 MIU	
	Diary No. Date of R & I & fee	Dy. No 12317 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	Innovator specification	
	Pack size & Demanded Price	50ml,100ml,250ml,500ml,1L,2.5L,5L, Plastic bottle.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Fenicol Liquid, 079134, Univet Pharmaceuticals, Rawalpindi.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Form-5 cover letter dully signed by management.	Firm has submitted fee challan No.74773392 dated 16-06-2022 of 7500/= along with signed form -5 along with Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision : Approved with innovator's specifications.		
543.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	COMBIGENT Injection	
	Composition	Each 100 ml contains: Gentamycin as sulphate……5 G Tylosin Tartarated……10 G Colistin Sulphate……20 MIU	

	Diary No. Date of R & I & fee	Dy. No 12152 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form - 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	Pack Size, Container and closure is not provided.
	Approval status of product in Reference Regulatory Authorities	Not Applicable
	Me-too status	Not verifiable
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Evidence of me-too status of product already registered in Pakistan. • Pre-registration variation fee challan.
	Decision: Deferred for following shortcomings: **1. Master Formulation with Complete Outline of manufacturing method is required.** **2. Complete finished good testing specifications mentioning assay of finished products.** **3. Pack Size, container and closure is not provided.** **4. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **5. Pre-registration variation fee challan.**	
544.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.
	Brand Name + Dosage Form + Strength	METABOLASE Injectable Solution
	Composition	Each 100 ml contains: L-Carnitine Hcl(613.3 mg)Equivalent to Carnitine..50 mg D.L Acetylmethionine ……...200 mg Cyanocobalamin…….0.2 m A-Tocopherol Acetate(33.0mg) Equivalent to A-Tocopherol……30 mg
	Diary No. Date of R & I & fee	Dy. No 12318 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Not provided
	Type of Form	Form - 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	Pack Size, Container and closure is not provided.

	Approval status of product in Reference Regulatory Authorities	Not Applicable
	Me-too status	METABOLASE INJECTABLE SOLUTION, 019904, FATRO S.P.A ITALY, PRIX PHARMACEUTICAL LAHORE
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Form-5 cover letter dully signed by management. • Pre-registration variation fee challan.
	Decision: Deferred for following shortcomings: **1. Master Formulation with Complete Outline of manufacturing method is required.** **2. Complete finished good testing specifications mentioning assay of finished products.** **3. Pack Size, container and closure is not provided.** **4. Form-5 cover letter dully signed by management.** **5. Pre-registration variation fee challan**	
545.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.
	Brand Name + Dosage Form + Strength	LINCOMICINA 150 GANADEXIL oral powder
	Composition	Each Gram contains: Lincomycin (as Hcl) ……...….150 mg
	Diary No. Date of R & I & fee	Dy. No 12321 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Broad spectrum antibiotic
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	100gm,1 kg,25 kg, plastic jar
	Approval status of product in Reference Regulatory Authorities	Not Applicable
	Me-too status	lincomicina 150 ganadexil oral powder, 078290, (manufactured by m/s. industrial veterinaria, s.a.-invesa, spain)., m/s. forward solutions,lahore.
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material

		management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Form-5 cover letter dully signed by management. • Brand name mentioned as oral powder where as route administration mentioned in form -5 is IM and IV.	Firm has submitted fee challan No.704535646224 dated 16-06-2022 of 30000/= along with signed form -5 mentioning Oral powder along with Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision : Approved		
546.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	NEMASOL PLUS	
	Composition	Oxyclozanide…….60 mg Levamisole…….30 mg Cobalt Sulphate…….3.34 mg Sodium Selenite…….1 mg	
	Diary No. Date of R & I & fee	Dy. No 12196 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anthelmintic and minerals	
	Type of Form	Form - 5	
	Finished product Specification	Innovator	
	Pack size & Demanded Price	100,250,500,1000 ml, plastic bottle.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Helmex Gold Drench, 057005, SELMORE PHARMACEUTICALS,LAHORE,	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for	

		the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Per gram powder composition is not mentioned. • Evidence of me-too status of product already registered in Pakistan.	Firm has submitted fee challan No.11184693 dated 16-06-2022 of 30000/= along with signed form -5 mentioning per ml composition as under: **Each ML Contain:** **Oxyclozanide……60 mg** **Levamisole as Hcl..30 mg** **Cobalt Sulphate….3.34 mg** **Sodium Selenite…….1 mg** Firm also provided Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision: Approved with innovator specification with following label claim; **Each ML Drench contain:** **Oxyclozanide……..…60 mg** **Levamisole……30 mg** **Cobalt Sulphate…….3.34 mg** **Sodium Selenite……1 mg**		
547.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	AMCOSIN powder	
	Composition	Each gram contains: Amoxycillin……100 mg Colistin Sulphate…….50 MIU Neomycin Sulphate……200 mg	
	Diary No. Date of R & I & fee	Dy. No 12321 A dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotics	
	Type of Form	Form - 5	
	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	100,250,500,1000 gm	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	AMCOCIN ORAL DRY POWDER, 083243, M/S. SELMORE PHARMACEUTICALS (PVT) LIMITED, LAHORE.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be	

		operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Per gram powder composition is not mentioned. • Form-5 mentioned route of administration as IM and IV whereas reference product is Oral powder.	Firm has submitted fee challan No.8171101756 dated 16-06-2022 of 30000/= along with signed form -5 mentioning oral route and revised composition as under: **Each kg Contain:** Amoxycillin Trihydrate eq. to Amoxicillin…...100 gm Colistin Sulphate...50 MIU Neomycin Sulphate….200g Firm also provided Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision: Approved with innovator specification with following label claim; **"Each kg Contain:** **Amoxycillin Trihydrate eq. to Amoxicillin……...100 gm** **Colistin Sulphate……...……..50 MIU** **Neomycin Sulphate……..……...200g"**		
548.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	FEBENSEL Suspension	
	Composition	Each ml Contains: Febentel……25mg	
	Diary No. Date of R & I & fee	Dy. No 12151 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anthelmintic	
	Type of Form	Form - 5	
	Finished product Specification	innovator Specification	
	Pack size & Demanded Price	250 ml,500 ml,1000ml,5000ml.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	FEBANTEL ORAL LIQUID, 058715, SELMORE PHARMACEUTICALS (PVT) LTD LAHORE	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and	

		Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • container and closure are not provided. • Undertaking at ending of Form-5	Firm has submitted reply with fee challan No. 0119088516 dated 01-08-2022 of 7500/= along with signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as plastic bottles.
	Decision : Approved with innovator's specification.		
549.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	NOXYFLOR powder	
	Composition	Each Gram Contains: Florfenicol……..…100mg Oxytetracycline……..….300mg Neomycin……..150mg	
	Diary No. Date of R & I & fee	Dy. No 12310 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antibiotics	
	Type of Form	Form - 5	
	Finished product Specification	Innovator	
	Pack size & Demanded Price	Jar,100 mg , 250 mg , 500 mg , 1000 mg	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	"NOXYFLOR WATER SOLUBLE POWDER, 087584, M/S. DIVINE PHARMACEUTICALS, LAHORE.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin)	

		Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form.	Firm has submitted reply with fee challan No. 26543666933 dated 01-08-2022 of 7500/= along with signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as plastic Jar.
	Decision : Approved with innovator's specification.		
550.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	AVIVIT Oral Solution	
	Composition	Each Litre Contains: Betaine as Hcl…….60Gm Choline as Chloride……180Gm Sorbitol……520Gm Vitamin B6……..12Gm Vitamin B3……..24Gm"	
	Diary No. Date of R & I & fee	Dy. No 12159 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Vitamins and amino acids	
	Type of Form	Form - 5	
	Finished product Specification	Innovators specification	
	Pack size & Demanded Price	1L,2L,5L,10L,25L,50 L,	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	ANIVIT LIQUID., 041299, ARTIMON, FRANCE., GHAZI BROTHERS, KARACHi.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required.	Firm has submitted reply with fee challan No. 62539026211 dated 01-08-2022 of 7500/= along with revised and signed

		• Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • Evidence of me-too status of already registered product. (Full fee required due to salt forms of APIs)	form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as plastic bottle.
	Decision : Approved with innovator's specification.		
551.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	TETRA DELTA Suspension Injection (Sterile)	
	Composition	Each ml Contains: Neomycin……..….105mg Procaine Penicillin G…….1000000 IU Novobiocin (As Sodium novobiocin) …….100mg Dihydrostreptomycin (As Dihydrostreptomycin Sulphate) ……100mg	
	Diary No. Date of R & I & fee	Dy. No 12304 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	24*10 ml	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	TETRA-DELTA STERILE SUSPENSION, 015480, UPJOHN LTD UK (manufacturer), UPJOHN ISLAMABAD (Importer)	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	

	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5. (Challan fee not submitted, change of formulation in label claim)	Firm has submitted reply along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as plastic bottle. Each ml Contains: 1-Neomycin as Sulphate……105mg 2-Procaine Penicillin G…….1000000 IU 3-Novobiocin (As Sodium novobiocin) …….100mg 4-Dihydrostreptomycin (As Dihydrostreptomycin Sulphate) ……..100mg 5.Prednisolone Acetate……..…10 mg
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
552.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	AVIPHOS Solution	
	Composition	Each Litre Contains: Calcium as Calcium Gluconate……..……....15Gm Phosphorus as Sodium Monobasic Phosphate…...110Gm Magnesium as Magnesium Chloride……..…„….22Gm Sodium as sodium Chloride……15Gm Iron as Iron II sulphate……..1500mg Zinc as Zinc Sulphate……....2200mg Manganese as manganese Sulphate…….…….2500mg Copper as Copper Sulphate……..…….110mg	
	Diary No. Date of R & I & fee	Dy. No 12157 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Mineral Mix supplement	
	Type of Form	Form - 5	
	Finished product Specification	Innovators specification	
	Pack size & Demanded Price	100ml,250 ml,500 ml,1 L,2 L,5L,10 L,25 L.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	041298, Artiphos Liquid,Ghazi brothers ,Khi.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as“ In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection”	

		Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • Evidence of me-too status of product already registered in Pakistan. (Full fee required due to salt forms of APIs)	• Firm has submitted replies with fee challan No. 289653847 dated 01-08-2022 of 7500/= and Challan No.8361231183 dated 03-09-2022 of 30000/= along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as plastic bottle.
	Decision : Approved with innovator's specification.		
553.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	UTAFIX Injection	
	Composition	Each 20ml Contains Oxytetracycline…….500mg Iodochlogroxy Quinolone……..500mg Furazolidone……...500mg Vitamin E……200mg	
	Diary No. Date of R & I & fee	Dy. No.12167 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotic with vitamin	
	Type of Form	Form - 5	
	Finished product Specification	Innovator specifation.	
	Pack size & Demanded Price	20 ml	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Uterous Injector Floor ,Reg No. 017913 ,mfg by : Floris Veterinary , Netherland , Import by : selmore Agencies Lahore.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing,machinery/equipment,material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General)	

		Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • Evidence of me-too status of product already registered in Pakistan.	• Firm has submitted reply with fee challan No. 289653847 dated 01-08-2022 of 7500/= along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as plastic bottle.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
554.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	SIPICON Injection	
	Composition	Each Dry Powder Vial Contains: Benzathine Penicillin…….....5000000 IU Procaine Penicillin……..…….. 15000000 IU Streptomycin Sulphate……..….5Gm	
	Diary No. Date of R & I & fee	Dy. No12306 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antibiotics	
	Type of Form	Form - 5	
	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	1'S	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	SIPICON INJECTION, 020844, SHAHEEN AGENCIES KARACHI (Importer)	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing,machinery/equipment,material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin)	

		Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • Undertaking to follow innovator brand as per 249th meeting of DRB. • Evidence of me-too status of already registered product.	Firm has submitted reply along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as Glass vial. (Challan Fee Not Submitted for preregistration variations)
	Decision: Approved with innovator specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
555.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	METABOLASE FORTE Injectable Solution	
	Composition	Each ml Contains: DL-Acetylmethionine 200mg Eq To Cyanocobalamin……...…0.2mg Carnitine Hcl…61.3mg Eq To Carnitine……. 50mg A-Tocopherol Acetate……. 30mg	
	Diary No. Date of R & I & fee	Dy. No12319 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Not provided	
	Type of Form	Form - 5	
	Finished product Specification	Not provided	
	Pack size & Demanded Price	Not provided	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	METABOLASE FORTE INJECTABLE SOLUTION, 043109, PRIX PHARMACEUTICA, LAHORE (Importer)	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing,machinery/equipment,material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin)	

		Liquid Injection (hormone) Liquid Injection (Steroid)
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • The applied composition does not resemble to mee to provided, i-e Metabolase Forte Injection. Submit revised label claim composition as per applied me to.
	Decision: Deferred for following shortcomings: • Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • The applied composition does not resemble to mee to provided, i-e Metabolase Forte Injection. Submit revised label claim composition as per applied me to.	
556.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.
	Brand Name + Dosage Form + Strength	BROCOTYD Water Soluble Powder
	Composition	Each 100Gm Contains: Doxycycline Hyclate……40Gm Tylosin Tartrate……20Gm Colistin Sulphate…….10Gm Bromhexin Hcl…….2Gm
	Diary No. Date of R & I & fee	Dy. No12315 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Broad spectrum antibiotics
	Type of Form	Form - 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	500 gm,1 kg
	Approval status of product in Reference Regulatory Authorities	Not Applicable
	Me-too status	BROCOTYD POWDER, 058962, UNIVET PHARMACEUTICAL RAWALPINDI
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing,machinery/equipment,material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)

	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • Undertaking to follow innovator brand as per 249th meeting of DRB. • Evidence of me-too status of registered product in Pakistan.	• Firm has submitted reply with fee challan No.4148868617 dated 01-08-2022 of 7500/= along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as plastic jar.
	Decision: Approved with innovator specification.		
557.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	SHATOPEN L.A Inj	
	Composition	Each ml Contains: Benzathine Penicillin G……..……100000 (IU) Procaine Penicillin G…… 100000 (IU) Dihydrostreptomycin Sulphate…….200mg	
	Diary No. Date of R & I & fee	Dy. No23307 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotics	
	Type of Form	Form - 5	
	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	50 ml	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	SHOTAPEN L.A. Injection, 022198, F.Y.Corporation Karachi.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing,machinery/equipment,material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	

	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • Evidence of me-too status of registered product in Pakistan.	Firm has submitted reply along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as Glass vial. (Pre-registration challan Fee 3000/ submitted vide challan No. 48230372 dated 29-08-2022)
	Decision: Approved with innovator specification.		
558.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	MULTIJECT IMM Injection	
	Composition	Each 5Gm Contains: Procaine Penicillin……1000000IU Streptomycin Sulphate……100mg Neomycin Sulphate…….100mg Prednisolone……10mg	
	Diary No. Date of R & I & fee	Dy. No 12305 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antibiotics and steroid combination	
	Type of Form	Form - 5	
	Finished product Specification	Innovator specification	
	Pack size & Demanded Price	24*5 gm	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	MULTIJECT IMM INJECTION, 018871, NAWAN TRADING CORP. KARACHI	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing,machinery/equipment,material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	

	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • Evidence of me-too status of registered product in Pakistan.	Firm has submitted reply along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as Glass vial. (Challan Fee Not Submitted for preregistration variations)
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
559.	Name and address of manufacturer/ Applicant	International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road,1-Km, towards Kahna, Lahore.	
	Brand Name + Dosage Form + Strength	I-Sterile Water of Injection (100 ml) (vet)	
	Composition	Each Vial Contains: Sterile Water for Injection…….100 ml	
	Diary No. Date of R & I & fee	Dy. No.218 (R&I) dated 27-08-2015; Rs.20,000/- dated 26-08-2015, **DUPLICATE DOSSIER** Dy.No.8504(R&I) dated 31-03-2022.	
	Pharmacological Group	Solvent / Diluent	
	Type of Form	Form-5	
	Finished product Specification	B.P Specifications.	
	Pack size & Demanded Price	100 ml glass vial, As per SRO	
	Approval status of product in Reference Regulatory Authorities		
	Me-too status		
	GMP status	GMP Inspection Certificate Ref No.44/2022-DRAP (AD-34697196-1037) issued on 13-04-2022 on the basis of inspection on 13-01-2022.	
	Remarks of the Evaluator	Undertaking to follow innovator brand as per 245th meeting of DRB	
	Decision: Deferred for submission for following shortcomings: • **Evidence of already approved product /generic /me too with registration number in Pakistan.** • **Indications and justifications for utilization of this product..**		
560.	Name and address of manufacturer/ Applicant	International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road,1-Km, towards Kahna, Lahore.	
	Brand Name + Dosage Form + Strength	I-Sterile Water of Injection (50 ml) (Vet) (Diluent)	
	Composition	Each Vial Contains: Sterile Water for Injection…….50 ml	
	Diary No. Date of R & I & fee	Dy. No.216 (R&I) dated 27-08-2015; Rs.20,000/- dated 26-08-2015, **DUPLICATE DOSSIER** Dy.No.8503(R&I) dated 31-03-2022.	
	Pharmacological Group	Solvent / Diluent	
	Type of Form	Form-5	
	Finished product Specification	B.P Specifications.	
	Pack size & Demanded Price	50 ml Glass vial, As per SRO	
	Approval status of product in Reference Regulatory Authorities	N/A	
	Me-too status	EACH VIAL CONTAINS: - WATER FOR INJECTION 50ML WATER FOR INJECTION, 020796, AMROS PHARMACEUTICALS KARACHI.	

	GMP status	GMP Inspection Certificate Ref No.44/2022-DRAP (AD-34697196-1037) issued on 13-04-2022 on the basis of inspection on 13-01-2022.
	Remarks of the Evaluator	Undertaking to follow innovator brand as per 245th meeting of DRB
	Decision: Approved.	
561.	Name and address of manufacturer/ Applicant	International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road,1-Km, towards Kahna, Lahore.
	Brand Name + Dosage Form + Strength	I-Sterile Water of Injection (500 ml) (vet)
	Composition	Each Vial Contains: Sterile Water for Injection…….500 ml
	Diary No. Date of R & I & fee	Dy. No.217 (R&I) dated 27-08-2015; Rs.20,000/- dated 26-08-2015, **DUPLICATE DOSSIER** Dy.No.8505(R&I) dated 31-03-2022.
	Pharmacological Group	Solvent/Diluent
	Type of Form	Form-5
	Finished product Specification	B.P Specifications.
	Pack size & Demanded Price	500 ml glass vial, As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	AQUA LITE DISTILLED WATER FOR INJECTION,500ml, 044977, LEADS PHARMA (PVT) LTD., ISLAMABAD
	GMP status	GMP Inspection Certificate Ref No.44/2022-DRAP (AD-34697196-1037) issued on 13-04-2022 on the basis of inspection on 13-01-2022.
	Remarks of the Evaluator	Undertaking to follow innovator brand as per 245th meeting of DRB
	Decision: Deferred for submission for following shortcomings: • **Evidence of already approved product /generic /me too with registration number in Pakistan.** • **Indications and justifications for utilization of this product..**	
562.	Name and address of manufacturer/ Applicant	Zakfas Pharmaceuticals (Pvt) Ltd. 12-Km, Lutafabad Bosan Road,Multan.
	Brand Name + Dosage Form + Strength	LEVAZAK Granules (Sachet)
	Composition	Each 100 gm Contains: Levamisol Hcl…… 15 % w/w
	Diary No. Date of R & I & fee	Dy. No.43(R&I) dated 21-01-2015; Rs.20,000/- dated 20-01-2015, **DUPLICATE DOSSIER** Dy.No.12070(R&I) dated 18-05-2022.
	Pharmacological Group	Anthelminthic
	Type of Form	Form-5
	Finished product Specification	Inhouse method
	Pack size & Demanded Price	10 g,50g,100g,200g,500g, 1000g.As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	NOBIMISOLE 15%.,062130, "NOBLE PHARMA, B-1 OLD INDUSTRIAL AREA, MIRPUR AZAD KASHMIR.
	GMP status	DML renewal inspection has been conducted on 15-06-2021 and panel recommended approval of newly upgrade(revised) Bolus section (Vet) and renewal of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
563.	Name and address of manufacturer/ Applicant	Zakfas Pharmaceuticals (Pvt) Ltd. 12-Km, Lutafabad Bosan Road,Multan.

	Brand Name + Dosage Form + Strength	ALBAZAK Bolus
	Composition	Each 5 gm Contains: Albendazole…….1gm
	Diary No. Date of R & I & fee	Dy. No.42(R&I) dated 21-01-2015; Rs.20,000/- dated 20-01-2015, **DUPLICATE DOSSIER** Dy.No.12071(R&I) dated 18-05-2022.
	Pharmacological Group	Anthelminthic
	Type of Form	Form-5
	Finished product Specification	Inhouse method
	Pack size & Demanded Price	5*100 sachet.As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	"UNI BABENZIN GRANULES,200 gm/Kg,(1 gm/5 gm), 094482, MANUFACTURER AND MARKETING AUTHORIZATION HOLDER:- M/S. UNI BIOTECH CO., LTD., 235-22, CHUSA-RO, SINAM-MYEON, YESAN-GUN, CHUNGCHEONGNAM-DO, SOUTH KOREA.
	GMP status	DML renewal inspection has been conducted on 15-06-2021 and panel recommended approval of newly upgrade(revised) Bolus section (Vet) and renewal of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
564.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	BREX Tablet 2 mg
	Composition	Each Tablet Contains: Brexpiprazole……2 mg
	Diary No. Date of R & I & fee	Dy. No 11956 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Atypical Antipsychotic
	Type of Form	Form – 5D
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	10's,20's,30, s, As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Tablet REXULTI 2mg, OTSUKA
	Me-too status	Not provided.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board.**	

565.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	ALLOP Tablet 100mg	
	Composition	Each Tablet contains: Allopurinol……100 mg	
	Diary No. Date of R & I & fee	Dy. No 11946 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antigout	
	Type of Form	Form – 5	
	Finished product Specification	USP Specification	
	Pack size & Demanded Price	10's,20's,30's,As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Allopurinol (100mg & 300mg) Tablets by M/s Accord healthcare limited, MHRA approved.	
	Me-too status	Zyuric-300 Tablet of M/s Rasco Pharma (Reg.#067966)	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No. 479530022 dated 22-06-2022 of 7500/=
	Decision : Approved.		
566.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	CLOBAZ Tablet 10mg	
	Composition	Each Tablet contains: Clobazam……10 mg	
	Diary No. Date of R & I & fee	Dy. No 11945 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Benzodiazepine, Psychotropic	
	Type of Form	Form – 5	
	Finished product Specification	BP Specification	
	Pack size & Demanded Price	10's,20's,30's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Onfi tablet (10mg, 20mg) by M/s Lundbeck Pharms LLC, USFDA Approved	
	Me-too status	Frisium tablet 10mg Reg No 002692	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • Section approval letter of psychotropic section from CLB.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No96028051264 dated 22-06-2022 of 7500/=. Firm inform that section approval from CLB is in process.

	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Psychotropic tablet section" from CLB.		
567.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	BREX Tablet 1 mg	
	Composition	Each Tablet Contains: Brexpiprazole……1 mg	
	Diary No. Date of R & I & fee	Dy. No 11954 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Atypical Antipsychotic	
	Type of Form	Form – 5D	
	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	10's,20's,30, s, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Tablet REXULTI 1mg, OTSUKA	
	Me-too status	Not provided.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board.**		
568.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	VALPOR Tablet 250 mg	
	Composition	Each Enteric Coated Tablet contains: Divalproex Sodium Eq. to Valproic Acid…….250 mg	
	Diary No. Date of R & I & fee	Dy. No 11949 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antipsychotic	
	Type of Form	Form – 5	
	Finished product Specification	USP Specification	
	Pack size & Demanded Price	10's,20's,30's,60's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Depakote (125mg, 250mg, 500mg) delayed-release tablets USFDA Approved	
	Me-too status	EPL 250mg Tablet by M/s Rotex Pharma (Reg# 100815)	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No.

			6464087798 dated 22-06-2022 of 7500/=.
	Decision : Approved.		
569.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	VALPOR Tablet 500 mg	
	Composition	Each Enteric Coated Tablet contains: Divalproex Sodium Eq. to Valproic Acid…….500 mg	
	Diary No. Date of R & I & fee	Dy. No 11948 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antipsychotic	
	Type of Form	Form – 5	
	Finished product Specification	USP Specification	
	Pack size & Demanded Price	10's,20's,30's,60's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Depakote (125mg, 250mg, 500mg) delayed-release tablets USFDA Approved	
	Me-too status	Dapakan Tablet 500mg, Platinum Pharma Reg. No. 024465.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No. 881327095652 dated 22-06-2022 of 7500/=.
	Decision : Approved.		
570.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	VONRAZ Tablet 10 mg	
	Composition	Each Film Coated Tablet contains: Vonoprazan Fumarate Eq.to Vonoprazan ……10 mg	
	Diary No. Date of R & I & fee	Dy. No 11980 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Potassium-Completive acid blocker	
	Type of Form	Form – 5	
	Finished product Specification	Innovator's Specification	
	Pack size & Demanded Price	10's,20's,30's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	TAKECAB 10mg Tablet of M/s Takeda (PMDA Approved)	
	Me-too status	Voniza 10mg Tablet of M/s Hilton Pharma	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No.

		• Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	32147046 dated 22-06-2022 of 7500/=. Firm intimated that they have submitted stability data on 21-02-2022.
	Decision: Deferred for evaluation of submitted stability studies data.		
571.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	VONRAZ Tablet 20 mg	
	Composition	Each Film Coated Tablet contains: Vonoprazan Fumarate Eq.to Vonoprazan ……20 mg	
	Diary No. Date of R & I & fee	Dy. No 11981 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Potassium-Completive acid blocker	
	Type of Form	Form – 5	
	Finished product Specification	Innovator's Specification	
	Pack size & Demanded Price	10's,20's,30's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	TAKECAB 20mg Tablet of M/s Takeda (PMDA Approved)	
	Me-too status	Voniza 20mg Tablet of M/s Hilton Pharma	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No. 551178055051 dated 22-06-2022 of 7500/=. Firm intimated that they have submitted stability data on 21-02-2022.
	Decision: Deferred for evaluation of submitted stability studies data.		
572.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	FLUTIN Capsule 20 mg	
	Composition	Each Capsule contains: Fluvastatin Sodium Eq.to Fluvastatin…….20 mg	
	Diary No. Date of R & I & fee	Dy. No 11968 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	HMG CoA reductase inhibitors	
	Type of Form	Form – 5	
	Finished product Specification	USP Specification	
	Pack size & Demanded Price	10's,20's,30's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA	
	Me-too status	Farmastin Capsules 20mg of Farmaceutics Int. Karachi.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot*	

		No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No. 02463888658 dated 22-06-2022 of 7500/=.
	Decision : Approved		
573.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	SILTAZ Tablet 50 mg	
	Composition	Each Tablet contains: Cilostazole……50 mg	
	Diary No. Date of R & I & fee	Dy. No 11971 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antiplatelet agent	
	Type of Form	Form – 5	
	Finished product Specification	Manufacturer specification	
	Pack size & Demanded Price	14's, 28's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	MHRA approved.	
	Me-too status	Prigtal Tablets, 036228, Getz Pharma, Karachi.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No. 86737321976 dated 22-06-2022 of 7500/=.
	Decision :Approved with innovator's specifications.		
574.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	BRIXAB Capsule 80 mg	
	Composition	Each Capsule Contains: Betrixaban Maleate eq. to Betrixaban…….. 80 mg	
	Diary No. Date of R & I & fee	Dy. No 11964 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Factor Xa Inhibitor	
	Type of Form	Form – 5	
	Finished product Specification	Innovator's specification	
	Pack size & Demanded Price	10's.20's,30's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Cap BEVYXXA 80mg, USFDA Marketing status discontinued,	
	Me-too status	Not provided.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	

	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • Status of submitted reference product is discontinued in reference regulatory authority. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.
	Decision: Deferred for following: • **Submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board.** • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.** • **Status of submitted reference product is discontinued in reference regulatory authority. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
575.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	ASINAP Tablet 5 mg
	Composition	Each Sublingual tablet Contains: Asenapine Maleate eq. to Asenapine…….5 mg
	Diary No. Date of R & I & fee	Dy. No 11973 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Antipsychotic
	Type of Form	Form – 5
	Finished product Specification	Innovator's specification
	Pack size & Demanded Price	20's,60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Not provided.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. Firm Informed that stability is under process, will be submitted once completed.
	Decision: Deferred for submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board.	
576.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	REXANT Tablet 15 mg
	Composition	Each Film Coated Tablet Contains: Suvorexant……15 mg
	Diary No. Date of R & I & fee	Dy. No 11975 dated 06-07-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Hypnotic/Sedative
	Type of Form	Form – 5

	Finished product Specification	Innovator's specification	
	Pack size & Demanded Price	10's, 20's.30's,As per SRO.	
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Tablet BELSOMRA 15 mg film coated tablet.	
	Me-too status	Not provided.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	Firm Informed that stability is under process, will be submitted once completed.
	Decision: Deferred for submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board.		
577.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	REXANT Tablet 20 mg	
	Composition	Each Film Coated Tablet Contains: Suvorexant……20 mg	
	Diary No. Date of R & I & fee	Dy. No 11976 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Hypnotic/Sedative	
	Type of Form	Form – 5	
	Finished product Specification	Innovator's specification	
	Pack size & Demanded Price	10's, 20's.30's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Tablet BELSOMRA 20 mg film coated tablet.	
	Me-too status	Not provided.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	Firm Informed that stability is under process, will be submitted once completed.
	Decision: Deferred for submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board.		

578.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	RUDIN Oral Solution	
	Composition	Each ml Contain: Rupatadine as Fumarate……1 mg	
	Diary No. Date of R & I & fee	Dy. No 11961 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Antiallergic	
	Type of Form	Form – 5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	10's, 20's.30's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	MHRA approved, Aspire Pharma, UK	
	Me-too status	Not provided	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	Firm Informed that stability is under process, will be submitted once completed.
	Decision: Deferred for submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board.		
579.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	RELOX 0.4mg/ml Injection	
	Composition	Each ml Contain: Naloxone Hydrochloride…….0.4 mg	
	Diary No. Date of R & I & fee	Dy. No 11941 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Opioid Antagonist	
	Type of Form	Form – 5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	1's,5's,10's ,25's,30's,50's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Naloxone of MHRA approved.	
	Me-too status	Naloxone Injection 0.4mg of M/s Rehman Medicines Co. (Reg.# 019587)	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format	Firm has submitted revised Form -5 on prescribed format

		of Drug (L, R&A) rules 1976. • Section approval letter from CLB.	along with challan fee. No. 1123289122 dated 22-06-2022 of 7500/=. Firm inform that section approval from CLB is in process.
	Decision: Approved.		
580.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	APRANT Capsule 80 mg	
	Composition	Each Capsule contain: Aprepitant ……...…….80 mg	
	Diary No. Date of R & I & fee	Dy. No 11945 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antiemetic	
	Type of Form	Form – 5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	2's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved	
	Me-too status	Apreon 80mg Capsules of M/s Ferozesons Labs, 068202	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No. 0663642988 dated 22-06-2022 of 7500/=.
	Decision: Approved.		
581.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	HYPIN Tablet 20 mg	
	Composition	Each Film coated Tablet Contains: Lercanidipine Hydrochloride…….…….20 mg	
	Diary No. Date of R & I & fee	Dy. No 11987 dated 06-07-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antihypertensive	
	Type of Form	Form – 5	
	Finished product Specification	Innovator's specification	
	Pack size & Demanded Price	7's,14's,28's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Lercadip 10mg of (MHRA approved)	
	Me-too status	095125, Canmap 10mg Tablet, Maple Pharmaceuticals (Pvt) Ltd.,Karachi	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	

	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No. 98840026 dated 22-06-2022 of 7500/=.
	Decision: Approved with innovators specifications.		
582.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	RANIGEN Effervescent Tablet 25 mg	
	Composition	Each Effervescent Tablet Contains: Ranitidine HCl Eq to Ranitidine……..……25 mg	
	Diary No. Date of R & I & fee	Dy. No 11954 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	H2 receptor Antagonist	
	Type of Form	Form – 5	
	Finished product Specification	Innovator's specification	
	Pack size & Demanded Price	7's,14's,28's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	USFDA marketing status as "Discontinued".	
	Me-too status		
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • **RRA status of Ranitidine containing products is suspended**.	Firm has submitted revised Form -5 on prescribed format along with challan fee. No. 708812425 dated 22-06-2022 of 7500/=
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products		
583.	Name and address of manufacturer/ Applicant	Medipak Limited,554 sundar Industrial Estate, Lahore.	
	Brand Name + Dosage Form + Strength	Medisol Medilyte-M Intravenous Infusion 1000ml	
	Composition	Each 1000ml contains: Calcium Chloride Dihydrate……0.22 gm Potassium Chloride……...1.5 gm Sodium Chloride……2.16 gm Sodium Acetate tri hydrate……3.13 gm Dextrose Anhydrous……50 gm	
	Diary No. Date of R & I & fee	Dy. No 12564 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Electrolytes	
	Type of Form	Form – 5	
	Finished product Specification	Manufacturer specifications	
	Pack size & Demanded Price	1000 ml,Poly Propylene (P.P) bottle with Euro cap, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Not Provided	
	Me-too status	PLYABOLYTE-M INJ, 011225, OTSUKA, Karachi. (Plabottle, not PP bottle)	

	GMP status	GMP certificate issued on 29-07-2021 based on inspection conducted on 21-05-2021 for Intravenous Infusion
	Remarks of the Evaluator	• Evidence of applied product in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan. • Revised master formulation as per revised label claim Mee-too reference of applied product with applied primary packaging (Poly Propylene) in Pakistan.
	Decision: Deferred for following shortcomings • **Evidence of applied product in RRA in applied primary packing of Polypropylene bottle.** • **Evidence of generic reference of applied product with applied primary packaging (Poly Propylene) registered in Pakistan.**	
584.	Name and address of manufacturer/ Applicant	Medipak Limited,554 sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Medisol Medilyte-M Intravenous Infusion 500 ml
	Composition	Each 1000 ml contains: Calcium Chloride Dihydrate……0.22 gm Potassium Chloride……...1.5 gm Sodium Chloride……2.16 gm Sodium Acetate tri hydrate……3.13 gm Dextrose Anhydrous……50 gm
	Diary No. Date of R & I & fee	Dy. No 12565 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Electrolytes
	Type of Form	Form – 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	500 ml, Poly Propylene (P.P) bottle with Euro cap, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Not Provided
	Me-too status	PLYABOLYTE-M INJ, 011225, OTSUKA, Karachi. (Plabottle, not PP bottle)
	GMP status	GMP certificate issued on 29-07-2021 based on inspection conducted on 21-05-2021 for Intravenous Infusion
	Remarks of the Evaluator	• Revised composition as per 500 ml pack • Evidence of applied product in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan. • Revised master formulation as per revised label claim • Mee-too reference of applied product with applied primary packaging (Poly Propylene) in Pakistan.
	Decision: Deferred for following shortcomings • **Revised composition as per 500 ml pack** • **Evidence of applied product in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan.** • **Revised master formulation as per revised label claim** • **Generic reference of applied product with applied primary packaging (Poly Propylene) in Pakistan**	
585.	Name and address of manufacturer/ Applicant	Medipak Limited,554 sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Medisol 0.45 NS + Dextrose Intravenous Infusion 500 ml
	Composition	Each 100 ml contains: Sodium Chloride……0.45 gm Dextrose Anhydrous……...5 gm
	Diary No. Date of R & I & fee	Dy. No 12563 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Electrolytes & Carbohydrate
	Type of Form	Form – 5

	Finished product Specification	USP Specs	
	Pack size & Demanded Price	500 ml, Poly Propylene (P.P) bottle with Euro Cap, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Not Provided	
	Me-too status	Sterifluid-DS 1/2 Infusion, 049285, Frontier Dextrose Ltd.Hattar.	
	GMP status	GMP certificate issued on 29-07-2021 based on inspection conducted on 21-05-2021 for Intravenous Infusion	
	Remarks of the Evaluator	• Evidence of applied product in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan. • Revised master formulation as per revised label claim • Me-too reference of applied product with applied primary packaging (Poly Propylene) in Pakistan.	
	Decision: Deferred for following shortcomings • **Evidence of applied product in RRA in applied primary packing of Polypropylene bottle** • **Generic reference of applied product with applied primary packaging (Poly Propylene)registered in Pakistan**		
586.	Name and address of manufacturer/ Applicant	Schazoo Zaka (Pvt) Ltd.,20 km, Lahore jaranwala road, Sheikhupura.	
	Brand Name + Dosage Form + Strength	PREGAB Capsule 75 mg	
	Composition	Each Capsule Contains: Pregabalin……...75 mg	
	Diary No. Date of R & I & fee	Dy. No 13063 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antiepileptic	
	Type of Form	Form – 5	
	Finished product Specification	Manufacturer Specifications	
	Pack size & Demanded Price	10's. As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Lyrica 75 mg capsule of Upjohn UK limited (MHRA) Approved)	
	Me-too status	Bargan 75mg Capsule, 094931, CKD Pharmaceuticals Pakistan (Pvt) Ltd.,Karachi	
	GMP status	GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb) Firm has also submitted GMP inspection report conducted on 31-03-2022 and recommended that firm had maintained good level of GMP compliance as per schedule B-II on Drug (Licensing, Registration & Advertising) rules,1976 at the time of inspection.	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976 along with preregistration variation fee. • Product is in USP, submit revised Finished product specification.	Firm has submitted reply along with revised and prescribed form-5. Firm has submitted their own testing specification; however, the monograph is present in USP. Firm did not submit preregistration variation fee.
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
587.	Name and address of manufacturer/ Applicant	Schazoo Zaka (Pvt) Ltd.,20 km, Lahore jaranwala road, Sheikhupura.	

	Brand Name + Dosage Form + Strength	PREGAB Capsule 150 mg	
	Composition	Each Capsule Contains: Pregabalin……...150 mg	
	Diary No. Date of R & I & fee	Dy. No 13062 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antiepileptic	
	Type of Form	Form – 5	
	Finished product Specification	Manufacturer Specifications	
	Pack size & Demanded Price	10's. As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Lyrica 150 mg capsule of Upjohn UK limited (MHRA) Approved)	
	Me-too status	Freglin Capsule 150 mg, 094034, FYNK Pharmaceuticals, Lahore.	
	GMP status	GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb) Firm has also submitted GMP inspection report conducted on 31-03-2022 and recommended that firm had maintained good level of GMP compliance as per schedule B-II on Drug (Licensing, Registration & Advertising) rules,1976 at the time of inspection.	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976 along with preregistration variation fee. • Product is in USP, submit revised Finished product specification.	Firm has submitted reply along with revised and prescribed form-5. Firm has submitted their own testing specification; however, the monograph is present in USP. Firm did not submit preregistration variation fee.
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
588.	Name and address of manufacturer/ Applicant	Schazoo Zaka (Pvt) Ltd.,20 km, Lahore jaranwala road, Sheikhupura.	
	Brand Name + Dosage Form + Strength	PREGAB Capsule 300 mg	
	Composition	Each Capsule Contains: Pregabalin……...300 mg	
	Diary No. Date of R & I & fee	Dy. No 13061 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antiepileptic	
	Type of Form	Form – 5	
	Finished product Specification	Manufacturer Specifications	
	Pack size & Demanded Price	10's. As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Lyrica 300 mg capsule of Upjohn UK limited (MHRA) Approved)	
	Me-too status	Newgaba 300mg Capsules, 092105, Biolabs (Pvt) Ltd., Islamabad	
	GMP status	GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb) Firm has also submitted GMP inspection report conducted on 31-03-2022 and recommended that firm had	

		maintained good level of GMP compliance as per schedule B-II on Drug (Licensing, Registration & Advertising) rules,1976 at the time of inspection.	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976 along with preregistration variation fee. • Product is in USP, submit revised Finished product specification.	Firm has submitted reply along with revised and prescribed form-5. Firm has submitted their own testing specification; however, the monograph is present in USP. Firm did not submit preregistration variation fee.
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/=as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
589.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	C-THROCIN Tablet 250 mg	
	Composition	Each Film Coated Tablet Contains: Clarithromycin…….250 mg	
	Diary No. Date of R & I & fee	Dy. No 12603 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Quinolone Antibiotic	
	Type of Form	Form – 5	
	Finished product Specification	B.P specification	
	Pack size & Demanded Price	,As per DPC	
	Approval status of product in Reference Regulatory Authorities	BIAXIN® (clarithromycin 250mg) film coated tablets, USFDA approved.	
	Me-too status	Claramed 250mg Tablets, Global Pharma, R.No. 023993.	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete manufacturing out line. • Complete finished product testing.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter.
	Decision: Approved with BP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
590.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	C-THROCIN Suspension 250 mg	
	Composition	Each 5ml Contains: Clarithromycin (taste masked granules 27.5%) .....250 mg	
	Diary No. Date of R & I & fee	Dy. No 12586 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Quinolone Antibiotic	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/USP	
	Pack size & Demanded Price	60 ml, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Biaxin Suspension (USFDA approved)	
	Me-too status	Maclacin of M/s Bosch	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (	

		G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation • Complete manufacturing out line. • Complete finished product testing specifications. (USP) • Form-5 Signed by Firms management. • Source of pellets with COA, Stability and GMP of source.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter.
	Decision: Approved with USP specification. Firm shall declare source of granules/pellets, GMP, COA and stability study data before issuance of registration letter. The firm shall submit applicable preregistration variation fee as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
591.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	LAMIDE Tablet 200 mg	
	Composition	Each Film Coated Tablet Contains: Lacosamide……200 mg	
	Diary No. Date of R & I & fee	Dy. No 12622 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antiepileptic	
	Type of Form	Form – 5	
	Finished product Specification	Not provided	
	Pack size & Demanded Price	Not provided, As per DPC	
	Approval status of product in Reference Regulatory Authorities	VIMPAT (50mg, 100mg, 150mg, 200mg) film coated tablet USFDA approved	
	Me-too status	Lacolit 200mg Tablet by M/s The Searle Company Limited, (Reg#077125)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G), Capsule (G), Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation • Complete manufacturing out line. • Complete finished product testing specifications. • Form-5 Signed by Firms management • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, Section approval letter.
	Decision: Approved with innovator specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
592.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	LAMIDE Tablet 100 mg	
	Composition	Each Film Coated Tablet Contains: Lacosamide……100 mg	
	Diary No. Date of R & I & fee	Dy. No 12620 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antiepileptic	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	Not provided, As per DPC	

	Approval status of product in Reference Regulatory Authorities	MHRA Approved film coated 100 mg tablet, Torrent Pharma,UK.	
	Me-too status	Lacogit-100 100mg Tablets, Reg # 083580, Glitz Pharma, Islamabad	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation • Complete manufacturing out line. • Complete finished product testing specifications. • Form-5 Signed by Firms management • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter.
	Decision: Approved with innovator specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
593.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	LAMIDE Tablet 50 mg	
	Composition	Each Film Coated Tablet Contains: Lacosamide……50 mg	
	Diary No. Date of R & I & fee	Dy. No 12621 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antiepileptic	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	Not provided, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Lacosamide Aspire 50 mg film-coated tablets by Aspire Pharma Limited. MHRA Approved	
	Me-too status	Lalap 50mg tablet. Reg. No. 70470	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation • Complete manufacturing out line. • Complete finished product testing specifications. • Form-5 Signed by Firms management • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with innovator specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
594.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	ONDOR Tablet 4 mg	
	Composition	Each Film Coated Tablet Contains: Ondansetron (as Hcl)……4 mg	
	Diary No. Date of R & I & fee	Dy. No 12591 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Selective Serotonin 5HT3 Receptor Antagonist	
	Type of Form	Form – 5	
	Finished product Specification	USP	

	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	MHRA Approved	
	Me-too status	Onden 4mg tablet of M/s Macter (Reg. # 057754)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Revised label claim as USP with Master Formulation • Complete manufacturing out line. • Complete finished product testing specifications. (USP) • Form-5 Signed by Firms management • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
595.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	ONDOR Tablet 8 mg	
	Composition	Each Film Coated Tablet Contains: Ondansetron (as Hcl).……8 mg	
	Diary No. Date of R & I & fee	Dy. No 12626 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Selective Serotonin 5HT3 Receptor Antagonist	
	Type of Form	Form – 5	
	Finished product Specification	USP	
	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	MHRA Approved	
	Me-too status	Onfran Tablet 8mg of M/s Al-Habib Pharma (Reg.# 059257)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G), Capsule (G), Dry Powder Suspension (G), Liquid (G), and Sachet (G).	
	Remarks of the Evaluator	• Revised label claim as USP with Master Formulation • Complete manufacturing out line. • Complete finished product testing specifications. (USP) • Form-5 Signed by Firms management • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
596.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	DEXFEN Tablet 200 mg	
	Composition	Each Film Coated Tablet Contains: Dexibuprofen.……200 mg	

	Diary No. Date of R & I & fee	Dy. No 12632 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	NSAID	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/innovator	
	Pack size & Demanded Price	30's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Atriscal 200 mg - film-coated tablets of Gebro Pharma GmbH, Approved in Austria.	
	Me-too status	Haltrin 200mg Tablet by M/s Brookes Pharmaceuticals, Karachi. (Reg. # 061068).	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specifications. (Innovator). • Form-5 Signed by Firms management. • Pack size	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with inovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
597.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	DEXFEN Tablet 300 mg	
	Composition	Each Film Coated Tablet Contains: Dexibuprofen……300 mg	
	Diary No. Date of R & I & fee	Dy. No 12633 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	NSAID	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/innovator	
	Pack size & Demanded Price	30's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 300 mg film-coated tablets MHRA Approved	
	Me-too status	Tercica 300mg Tablet. Reg. No. 58445	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specifications. (Innovator). • Form-5 Signed by Firms management. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
598.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	DEXFEN Tablet 400 mg	
	Composition	Each Film Coated Tablet Contains:	

		Dexibuprofen……400 mg	
	Diary No. Date of R & I & fee	Dy. No 12585 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	NSAID	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/ Innovator	
	Pack size & Demanded Price	30's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 400 mg film-coated tablets MHRA Approved	
	Me-too status	Tercica 400mg Tablet. Reg. No. 58446	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specifications. (Innovator). • Form-5 Signed by Firms management. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
599.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	HAEMREN Capsule 250 mg	
	Composition	Each Capsule Contains: Tranexamic Acid.……250 mg	
	Diary No. Date of R & I & fee	Dy. No 12630 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antifibrolytics	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / JP/BP	
	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	TRANEX 250 mg capsule, AIFA approved.	
	Me-too status	Tranxet 250mg Capsules, 084338, Biolabs (Pvt) Ltd., Islamabad	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Complete manufacturing out line. • Complete finished product testing specifications. (JP). • Form-5 Signed by Firms management. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with JP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		

600.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	HAEMREN Capsule 500 mg	
	Composition	Each Capsule Contains: Tranexamic Acid.……500 mg	
	Diary No. Date of R & I & fee	Dy. No 12631 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Hemostatics, (Amino acid antifibrinolytics) (B02AA02)	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/ JP/BP	
	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	TRANEX 500 mg capsule, AIFA approved.	
	Me-too status	Ephamic Capsules 500mg, 096273, E-Pharm Laboratories, Karachi	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specifications. (JP). • Form-5 Signed by Firms management. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with JP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
601.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	PENICIL Tablet 250 mg	
	Composition	Each Film Coated Tablet Contains: Penicillamine……250 mg	
	Diary No. Date of R & I & fee	Dy. No 12628 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antirheumatic Agent	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/JP	
	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Penicillamine 250 mg film-coated tablets of MHRA approved	
	Me-too status	Penicillamine 250mg Tablet of M/s Medisure Lab Reg no # 083907	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specifications. (JP). • Form-5 Signed by Firms management. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with JP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		

602.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	APRANT Capsule 125 mg	
	Composition	Each Capsule Contains: Aprepitant……125 mg	
	Diary No. Date of R & I & fee	Dy. No 12598 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antiemetic	
	Type of Form	Form – 5	
	Finished product Specification	USP	
	Pack size & Demanded Price	3's,As per DPC	
	Approval status of product in Reference Regulatory Authorities	EMEND Capsule of USFDA	
	Me-too status	Apritus 125mg Capsule of M/s S.J&G	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Complete manufacturing out line. • Complete finished product testing specifications. (USP). • Form-5 Signed by Firms management. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with JP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
603.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	MINOLINE Tablet 100 mg	
	Composition	Each Film Coated Tablet Contains: Minocycline as Hydrochloride……100 mg	
	Diary No. Date of R & I & fee	Dy. No 12608 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Tetracycline antibiotics	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / USP	
	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	MHRA Approved	
	Me-too status	Minokane 100mg tablet by M/s Kanel Pharma, Islamabad. Registration No.099655	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specifications. (USP). • Form-5 Signed by Firms management. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.

	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
604.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	DELAS Capsule 60 mg	
	Composition	Each Capsule Contains: Dexlansoprazole (Enteric Coated pellets) ……60 mg	
	Diary No. Date of R & I & fee	Dy. No 12587 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Proton Pump Inhibitor	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	30's , As per DPC	
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA	
	Me-too status	Razodex of Getz Pharma	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Complete manufacturing out line. • Complete finished product testing specification. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Source of pellets with GMP, COA and stability study of pellets • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size. Firm has also submitted Source of Pellets as m/s Vision Pharmaceuticals (Pvt) Ltd along with stability study data, COA.
	Decision :Deferred for submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.		
605.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	RIVBAN Tablet 20 mg	
	Composition	Each Film Coated Tablet Contains: Rivaroxaban ……20 mg	
	Diary No. Date of R & I & fee	Dy. No 12611 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antithrombotic Agent	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/BP	
	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Rivaroxaban 20 mg film-coated tablets, MHRA approved.	
	Me-too status	Xarelto 20Mg Tablets, Bayer Pakistan, Reg. No. 072550.	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	

	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specification. (BP) • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with B.P specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
606.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	TERBIN Tablet 125 mg	
	Composition	Each Tablet Contains: Terbinafine as Hcl ……125 mg	
	Diary No. Date of R & I & fee	Dy. No 12581 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antifungal	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Lamisil® Tablets 250mg by M/s Novartis Pharmaceuticals UK Limited,MHRA Approved.	
	Me-too status	Logirid Tablet 250mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80847	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specification. (Innovator) • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
607.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	URDEOIC Suspension	
	Composition	Each 5 ml Contains: Ursodeoxycholic Acid……250 mg	
	Diary No. Date of R & I & fee	Dy. No 12607 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anti-Cholelithic Acid /Bile acid Preparation	
	Type of Form	Form – 5	
	Finished product Specification	Not provided /BP	
	Pack size & Demanded Price	120 ml, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Ursofalk 250mg/5ml Suspension MHRA approved	
	Me-too status	Urolic 250mg/5ml Oral Suspension by M/s Pharmasol (Pvt) Ltd (Reg#099706)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	

	Remarks of the Evaluator	• Master formulation is required. • Complete finished product testing specification. • Section Approval letter from CLB • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with BP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
608.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	RICE ORS Sachet	
	Composition	Each Sachet Contains: Rice Powder (Pre cooked) …….6 g Sodium Citrate ……...0.58 g Sodium Chloride…….0.35 g Potassium Chloride…….0.30 g	
	Diary No. Date of R & I & fee	Dy. No 12629 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Electrolyte/Antidiarrheal	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/Innovator	
	Pack size & Demanded Price	10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Dioralyte Relief (MHRA Approved)	
	Me-too status	HILYTE-R powders by M/s Hilton pharma,(Reg#073733),	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master formulation. • Complete finished product testing specification (Innovator) • Section Approval letter form CLB. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter, and pack size.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
609.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	BIOFEN Sachet 600 mg	
	Composition	Each Sachet Contains: IBUPROFEN……600 mg (Effervescent Granules)	
	Diary No. Date of R & I & fee	Dy. No 12619 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	NSAID	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Brufen Granules (MHRA approved)	
	Me-too status	Brufen 600mg Sachet, Abbott Laboratories, Reg. No. 044414.	

	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master formulation. • Complete finished product testing specification (Innovator) • Section Approval letter form CLB. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
610.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	GASTRO Sachet	
	Composition	Each Sachet Contain: Dioctahedral smectite…….3.00 g	
	Diary No. Date of R & I & fee	Dy. No 12588 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Intestinal Adsorbents	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	30's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved	
	Me-too status	Semetamed 3g Sachet of M/s Mediate Pharmaceutical (Pvt.) Ltd, Karachi,061925	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master formulation. • Complete finished product testing specification (Innovator) • Section Approval letter form CLB. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, outline of manufacturing method, Section approval letter and pack size.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
611.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	MEBINE Sachet	
	Composition	Each Sachet Contains: Mebeverine Hcl…….135 mg Ispaghula Husk……..3.5 g	
	Diary No. Date of R & I & fee	Dy. No 12625 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antispasmodic	
	Type of Form	Form – 5	
	Finished product Specification	Not provided	
	Pack size & Demanded Price	6.335 * 10's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Fybogel Mebeverine effervescent granules by M/s Reckitt Benckiser Healthcare (UK) Ltd. (MHRA approved)	

	Me-too status	Colospas Fibro 135mg/3.5g powder by M/s Nabiqasim. (Reg# 058672)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master formulation. • Complete finished product testing specification (Innovator). • Section Approval letter form CLB. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, Section approval letter, and pack size.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
612.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	ACETIN Sachet	
	Composition	Each Sachet Contain: Acetylcysteine …….200 mg	
	Diary No. Date of R & I & fee	Dy. No 12594 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Expectorant	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	30's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Acetylcysteine 200 mg Powder for Oral Solution by M/s NTC S.r.l. (MHRA approved	
	Me-too status	Mucolator 200mg powders by M/s Abbott Laboratories. (Reg# 017693)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master formulation. • Complete finished product testing specification (Innovator) • Section Approval letter form CLB. • Pack size.	Firm has submitted reply along with Form-5 dully signed by Firm management with annexure including master formulation, Section approval letter, and pack size.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
613.	Name and address of manufacturer/ Applicant	Goodman Labortories(Pvt) Ltd,Plot No. 5 , St No. S-5,National Industrial Zon,Rawat,Islamabad.	
	Brand Name + Dosage Form + Strength	BET Tablet 75 mg	
	Composition	Each Film Coated Tablet Contains: Irbesartan…….75 mg	
	Diary No. Date of R & I & fee	Dy. No 11741 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Angiotension II receptor antagonist	
	Type of Form	Form – 5	
	Finished product Specification	BP	
	Pack size & Demanded Price	10's'20's30's,60's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Aprovel (75mg, 150mg, 300mg) film coated tablet by M/s Sanofi Aventis, MHRA Approved.	
	Me-too status	Gooday-H Tablets 300mg, by M/s Wilson, Reg No. 75366	

	GMP statu	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Tablet. • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
614.	Name and address of manufacturer/ Applicant	Goodman Labortories(Pvt) Ltd,Plot No. 5 , St No. S-5,National Industrial Zon,Rawat,Islamabad.
	Brand Name + Dosage Form + Strength	T-SART Tablet 40 mg
	Composition	Each Tablet Contains: Telmisartan…….40 mg
	Diary No. Date of R & I & fee	Dy. No 11725 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antihypertensive
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's'20's30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Telmisartan Mylan 40 mg uncoated tablets, MHRA Approved.
	Me-too status	Misar 40mg Tablet, Highnoon Laboratories, Reg. No. 065687.
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Tablet. • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
615.	Name and address of manufacturer/ Applicant	Goodman Labortories(Pvt) Ltd,Plot No. 5 , St No. S-5,National Industrial Zon,Rawat,Islamabad.
	Brand Name + Dosage Form + Strength	FIBREN Capsule 67 mg
	Composition	Each Capsule Contains: Fenofibrate…….67 mg
	Diary No. Date of R & I & fee	Dy. No 11731 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Lipid Reducing Agent
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's'20's30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Fenofibrate 67mg capsules Actavis Barnstaple UK (MHRA approved)
	Me-too status	Fenoget 67mg micronized capsules of M/s Getz Pharmaceuticals,Karachi.(047197)
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Capsule.

		• DML renewal status from CLB. • Section Approval letter form CLB. • Pack size.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
616.	Name and address of manufacturer/ Applicant	Goodman Labortories(Pvt) Ltd,Plot No. 5 , St No. S-5,National Industrial Zon,Rawat,Islamabad.
	Brand Name + Dosage Form + Strength	ROXET CR Tablet 12.5 mg
	Composition	Each Controlled Release Tablet Contains: Paroxetine as HCl…….12.5 mg
	Diary No. Date of R & I & fee	Dy. No 11739 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	SSRI /Anti-Depressant
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	PAXIL CR (paroxetine 25 mg) film coated tablets, USFDA approved.
	Me-too status	Parxet 25mg Tablets/s Biolabs Islamabad, 084343
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Tablet. • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
617.	Name and address of manufacturer/ Applicant	Goodman Labortories(Pvt) Ltd,Plot No. 5 , St No. S-5,National Industrial Zon,Rawat,Islamabad.
	Brand Name + Dosage Form + Strength	VILMET Tablet 50/500 mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin …….50 mg Metformin Hcl…….500 mg
	Diary No. Date of R & I & fee	Dy. No 11736 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antidiabetic
	Type of Form	Form – 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's,14's,20's,28's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Eucreas 50/500mg film coated tablet, Novartis Pharma, Germany (MHRA)
	Me-too status	Galvus Met (50mg/500mg) tablet by Novartis Pharma, Reg. No.078106.
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Tablet. • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	

618.	Name and address of manufacturer/ Applicant	Goodman Labortories(Pvt) Ltd,Plot No. 5 , St No. S-5,National Industrial Zon,Rawat,Islamabad.	
	Brand Name + Dosage Form + Strength	ZOMID Capsule 50 mg	
	Composition	Each Capsule Contains: Zonisamide ……50 mg	
	Diary No. Date of R & I & fee	Dy. No 11721 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antiepileptic	
	Type of Form	Form – 5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	10's,14's,20's,30's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Zonisamide Warren 50mg capsule MHRA Approved	
	Me-too status	Seizof 50mg Capsule of OBS Pakistan Reg#73643)	
	GMP status	Not provided within last 3 years	
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Master formulation mentioned API Fenofibrate instead of Zonisamide. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Capsule • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size.	
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**		
619.	Name and address of manufacturer/ Applicant	Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.	
	Brand Name + Dosage Form + Strength	DICTIL Tablet	
	Composition	Each Enteric Coated Tablet Contains: Misoprostol…….200 Mcg Diclofenac Sodium……..75 mg	
	Diary No. Date of R & I & fee	Dy. No 11701 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Prostaglandin E1 Analogue, NSAID	
	Type of Form	Form-5	
	Finished product Specification	Innovator's Specification	
	Pack size & Demanded Price	2*10's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Arthrotec of USFDA Approved	
	Me-too status	Cytopan-75 Tablets by Getz Pharma (Reg#024014)	
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)	
	Remarks of the Evaluator	• Firm does not mention as "enteric Coated inner tablet of Diclofenac Sodium" in form-5.	• Firm has submitted reply with fee challan No.09189046503 dated 03-08-2022 of 30000/=along with revised form-5 with USP

		• Form-5 and Master formulation does not mentioned Misoprostol in 1 % HPMC dispersion. • Evidence of facility of manufacturing of Tablet within tablet formulation (Bilayer Tablet Machine). • USP monograph is available	specification of finished drug product mentioning • Each Bilayer Tablet Contains: "Enteric coated inner tablet of Diclofenac Sodium ….75 mg. Misoprostol ameliorated with 1 % HPMC eq. to Misoprostol …...200 mcg" Firm has submitted revised master formulation for bilayer tablet with manufacturing method through Bilayer Tablet machine. Firm has submitted copy of Invoice of bilayer Tablet machine dated 25-06-2022.
	Decision: Approved with innovator's specifications,the firm shall submit Installation Qualification (IQ) , Operational qualification (OQ) before issuance of registration letter.		
620.	Name and address of manufacturer/ Applicant	Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.	
	Brand Name + Dosage Form + Strength	HYOSCINE PLUS Tablet	
	Composition	Each Film Coated Tablet Contains: Paracetamol …….….500 mg Hyoscine Butyl bromide ……...10 mg	
	Diary No. Date of R & I & fee	Dy. No 11775 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Spasmodic,Analgesic	
	Type of Form	Form-5	
	Finished product Specification	Innovator's Specification	
	Pack size & Demanded Price	100's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Buscopan Plus film-coated tablet. DMDI Germany approved.	
	Me-too status	Hyo-Plus Tablets. Reg. No. 064452 (film-coated) of M/s. Roryan Pharmaceuticals.	
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)	
	Remarks of the Evaluator	Already registered.	
	Decision: Registration Board disposed of application with no further action as applied formulation has already been registered in the name of M/s Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.		
621.	Name and address of manufacturer/ Applicant	Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.	
	Brand Name + Dosage Form + Strength	ABESTATIN Tablet 20 mg	
	Composition	Each Film Coated tablet contains: Atorvastatin Calcium Eq. to Atorvastatin……20mg	
	Diary No. Date of R & I & fee	Dy. No 11799 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	

	Pharmacological Group	Antilipidemic	
	Type of Form	Form-5	
	Finished product Specification	USP	
	Pack size & Demanded Price	10's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	MHRA approved, 20 mg Film coating Tablets.	
	Me-too status	LIPIGET TABLETS 20mg (Reg. No.: 029957) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi	
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)	
	Remarks of the Evaluator	• Firm does not mention as "Film Coated tablet" in form-5. • Revised label claim and composition as "Each Film Coated tablet contains: Atorvastatin calcium trihydrate eq to Atorvastatin 20 mg	•Firm has submitted reply with fee challan No.036783126358 dated 03-08-2022 of 7500/=along with revised form-5 and master formulation mentioning label claim as; Each film Coated tablet Contains: Atorvastatin calcium trihydrate eq to Atorvastatin Calcium……20 mg
	Decision: Approved.		
622.	Name and address of manufacturer/ Applicant	Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.	
	Brand Name + Dosage Form + Strength	THYROXINE Tablet	
	Composition	Each tablet contains: Thyroxin Sodium…….50 Mcg	
	Diary No. Date of R & I & fee	Dy. No 11790 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Thyroid Hormone	
	Type of Form	Form-5	
	Finished product Specification	Innovator Specifications (USP)	
	Pack size & Demanded Price	100's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Uncoated tablet Levothyroxine Sodium 50 mcg.	
	Me-too status	M/s GlaxoSmithKlin Pakistan Limited, 000374	
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)	

	Remarks of the Evaluator	• The reference product contains Levothyroxine Sodium 50 mcg per tablet where as applied product contains thyroxine Sodium 50 mcg, submit revised form-5 with label claim as per reference product. • Section approval letter of hormone section from CLB. • Pharmacological Group is not mentioned in form -5. • Finished product monograph as per USP.
	Decision: Deferred for following shortcomings: • **The reference product contains Levothyroxine Sodium 50 mcg per tablet where as applied product contains thyroxine Sodium 50 mcg, submit revised form-5 with label claim as per reference product.** • **Section approval letter of hormone section from CLB is required.** • **Pharmacological Group is not mentioned in form -5.** • **Finished product monograph as per USP**	
623.	Name and address of manufacturer/ Applicant	Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.
	Brand Name + Dosage Form + Strength	LETRO Tablet 2.5 mg
	Composition	Each Film Coated tablet contains: Letrozole…….…….2.5 mg
	Diary No. Date of R & I & fee	Dy. No 11794 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Aromatase inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3*10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	FEMARA 2.5mg film coated tablet USFDA Approved
	Me-too status	Letzole 2.5mg Tablet by M/s Opal Labs (Reg#075805)
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)
	Remarks of the Evaluator	• Firm does not mention as "Film Coated tablet" in form-5. Submit revised Form-5 with label claim as per reference product. •Firm has submitted reply with fee challan No.1590869186 dated 03-08-2022 of 7500/=along with revised form-5 and master formulation mentioning label claim as; Each film Coated Tablet Contains: Letrozole……..2.5 mg
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
624.	Name and address of manufacturer/ Applicant	Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.
	Brand Name + Dosage Form + Strength	IBUNAC FORTE TABLET
	Composition	Each Film Coated Tablet Contains: Ibuprofen…….……..400 mg Pseudoephedrine……..60 mg

	Diary No. Date of R & I & fee	Dy. No 11776 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Analgesic, Antipyretic, Nasal Decongestant	
	Type of Form	Form-5	
	Finished product Specification	USP	
	Pack size & Demanded Price	10*10's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Lasynac Max Strength 400mg/60mg film coated tablets (MHRA Approved)	
	Me-too status	Alvry Forte Tablet by M/s The Schazoo Pharmaceutical Laboratories (Reg#087563)	
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)	
	Remarks of the Evaluator	• Firm does not mention as "Film Coated tablet" in form-5. • Reference product label claim is Pseudoephedrine HCl, Revised label claim on form-5 as pseudoephedrine HCl 60 mg is required.	•Firm has submitted reply with fee challan No.9672048438 dated 03-08-2022 of 7500/=along with revised form-5 and master formulation mentioning label claim as; Each film Coated Tablet Contains: Ibuprofen……400 mg Pseudoephedrine Hcl..60 mg
	Decision: Approved.		
625.	Name and address of manufacturer/ Applicant	Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.	
	Brand Name + Dosage Form + Strength	Q-SPAM Tablet	
	Composition	Each Sugar-Coated Tablet Contains: Phloroglucinol……80 mg Trimethyl Phloroglucinol……...80 mg	
	Diary No. Date of R & I & fee	Dy. No 11787 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antispasmodic	
	Type of Form	Form-5	
	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	3*10's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Spasfon, coated tablet by M/s Teva Sante, ANSM France Approved.	
	Me-too status	Gluwix Tablet 80/80mg by M/s Wnsfield, Reg. No. 097067	
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory	

		4. Sachet (general)	
	Remarks of the Evaluator	• Firm does not mention as "Sugar Coated tablet" in form-5. • Reference product contains "Phloroglucinol Hydrate". Revised Formulation of form -5 mentioning hydrated Phloroglucinol 80 mg.	•Firm has submitted reply with fee challan No.3899378886 dated 03-08-2022 of 7500/=along with revised form-5 and master formulation mentioning label claim as; Each Sugar-Coated Tablet Contains: Phloroglucinol Hydrate ……80 mg Trimethyl Phloroglucinol…....80 mg
	Decision:Approved with innovators specifications.		
626.	Name and address of manufacturer/ Applicant	Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.	
	Brand Name + Dosage Form + Strength	Q-SPA Tablet	
	Composition	Each Tablet Contains: Drotaverine……40 mg	
	Diary No. Date of R & I & fee	Dy. No 11788 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antispasmodic	
	Type of Form	Form-5	
	Finished product Specification	Innovator's Specification	
	Pack size & Demanded Price	20's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Approved in three EMA states as un-coated tablets in Hungary, Romania & Solvakia	
	Me-too status	Paspa Tablets of M/s Pliva Pharma 026881	
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)	
	Remarks of the Evaluator	• Firm 5 mentions "Each Tablet contains: Drotaverine 40 mg", whereas master formulation mentions drotaverine Hcl 40 mg. which needs correction.	•Firm has submitted reply with revised form -5 mentioning label claim as: **Each Tablet Contains:** **Drotaverine Hcl……40 mg**
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 30000/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
627.	Name and address of manufacturer/ Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 5, St No. S-5, National Industrial Zone, Rawat, Islamabad.	
	Brand Name + Dosage Form + Strength	PINE XR Tablet 150 mg	
	Composition	Each Extended Release Tablet Contains: Quetiapine as Fumarate….. ……150 mg	
	Diary No. Date of R & I & fee	Dy. No 11734 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Atypical Antipsychotic	
	Type of Form	Form – 5	

	Finished product Specification	USP specification
	Pack size & Demanded Price	10's,14's,20's,30's,50's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Seroquel XR of USFDA approved.
	Me-too status	Qusel XR 150mg Tablet of M/s Hilton Pharma
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Tablets. • DML renewal status from CLB. • Section Approval letter form CLB.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
628.	Name and address of manufacturer/ Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 5, St No. S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	VILMET Tablet 50/850 mg
	Composition	Each Film Coated Tablet Contains: Vidagliptin….. ……50 mg Metformin HCl…….850 mg
	Diary No. Date of R & I & fee	Dy. No 11737 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antidiabetic
	Type of Form	Form – 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's,14's,20's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Galvumet 50mg/850mg tablets by M/s. Novartis Pharmaceuticals Australia (TGA approved)
	Me-too status	Galvus Met 50mg/850mg tablets of M/s Novartis Pharma, Karachi
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Tablets. • DML renewal status from CLB. • Section Approval letter form CLB.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
629.	Name and address of manufacturer/ Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 5, St No. S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	VILMET Tablet 50/1000 mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin….. ……50 mg Metformin HCl…….1000 mg
	Diary No. Date of R & I & fee	Dy. No 11738 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antidiabetic
	Type of Form	Form – 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's,14's,20's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	MHRA approved, TEVA UK Limited, PL 00289/2175
	Me-too status	Vilda Plus 50/1000mg Tablet, Reg # 090282, Rotex Pharma (Pvt) Ltd., Islamabad,

	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Tablets. • DML renewal status from CLB. • Section Approval letter form CLB.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
630.	Name and address of manufacturer/ Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 5, St No. S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	DULEX Capsule 20 mg.
	Composition	Each Capsule Contains: Duloxetine as Hcl (as Enteric Coated Pellets) ……20 mg
	Diary No. Date of R & I & fee	Dy. No 11726 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	SUI (Stress Urinary Incontinence)
	Type of Form	Form – 5
	Finished product Specification	USP specification
	Pack size & Demanded Price	10's,20's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Cymbalta 30mg capsules by Lilly USA, LLC, (USFDA Approved)
	Me-too status	Dulact 30mg Capsule by Genome Pharmaceutical
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Manufacturing method /outline of Tubes of cream/ointment is provided instead of Capsules. • DML renewal status from CLB. • Section Approval letter form CLB. • Source of Pellets, COA, GMP of Source and Stability study data of 3 batches of Pellets (In case of foreign source of pellets, fee for source approval).
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
631.	Name and address of manufacturer/ Applicant	Goodman Laboratories (Pvt) Ltd., Plot No. 5, St No. S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	APRENT Capsule 40 mg.
	Composition	Each Capsule Contains: Aprepitant……40 mg
	Diary No. Date of R & I & fee	Dy. No 11715 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Neurokinin 1 (NKI) receptors antagonist, antiemetic agent
	Type of Form	Form – 5
	Finished product Specification	USP specification
	Pack size & Demanded Price	10's,14's,20's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Apreon 40mg Capsules of M/s Ferozesons Labs, 068201
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Master formulation mentioned API Fenofibrate instead of Aprepitant. • Manufacturing method /outline of tubes of cream/ointment is provided instead of Capsule

		• DML renewal status from CLB. • Section Approval letter form CLB.
	Decision: Deferred for following: • **Verification of validity staus of DML from Licensing Divison.** • **Submission of Manufacturing method /outline of applied product.**	
632.	Name and address of manufacturer/ Applicant	Baxter Pharmaceuticals (Pvt.) Ltd., A-1/A Scheme 33, Phase 1, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	NIPINE Capsule 5 mg
	Composition	Each Tablet Contains: Nifedipine…….5 mg
	Diary No. Date of R & I & fee	Dy. No 12078 dated 06-03-2019; Rs.20,000/- dated 27-02-2019.
	Pharmacological Group	Calcium Channel Blocker
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	Not Provided
	Approval status of product in Reference Regulatory Authorities	-
	Me-too status	-
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • In Covering letters, Form-5 Cover letter and Fee Challan, Capsule dosage form is mentioned. Where as in Form-5 annexure and master formulation, Tablet dosage form is mentioned which needs clarification/correction along with revised documents. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Finished Product testing specification not provided. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size not provided.
	Decision: Deferred for following shortcomings: • **GMP certificate/inspection conducted within last 3 years is** • **In Covering letters, Form-5 Cover letter and Fee Challan, Capsule dosage form is mentioned. Where as in Form-5 annexure and master formulation, Tablet dosage form is mentioned which needs clarification/correction along with revised documents.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Finished Product testing specification not provided.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **DML renewal status from CLB is required.** • **Section Approval letter form CLB is required.** • **Pack size not provided.**	
633.	Name and address of manufacturer/ Applicant	Baxter Pharmaceuticals (Pvt.) Ltd., A-1/A Scheme 33, Phase 1, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	NIPINE Capsule 20 mg
	Composition	Each Tablet Contains: Nifedipine…….20 mg
	Diary No. Date of R & I & fee	Dy. No 12080 dated 06-03-2019; Rs.20,000/- dated 27-02-2019.

	Pharmacological Group	Calcium Channel Blocker
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	Not Provided
	Approval status of product in Reference Regulatory Authorities	-
	Me-too status	-
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • In Covering letters, Form-5 Cover letter and Fee Challan, Capsule dosage form is mentioned. Where as in Form-5 annexure and master formulation, Tablet dosage form is mentioned which needs clarification/correction along with revised documents. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Finished Product testing specification not provided. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size not provided.
	Decision: Deferred for following shortcomings: • **GMP certificate/inspection conducted within last 3 years is** • **In Covering letters, Form-5 Cover letter and Fee Challan, Capsule dosage form is mentioned. Where as in Form-5 annexure and master formulation, Tablet dosage form is mentioned which needs clarification/correction along with revised documents.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Finished Product testing specification not provided.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **DML renewal status from CLB is required.** • **Section Approval letter form CLB is required.** • **Pack size not provided.**	
634.	Name and address of manufacturer/ Applicant	Baxter Pharmaceuticals (Pvt.) Ltd., A-1/A Scheme 33, Phase 1, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	AMSARTAN Tablet 20/10 mg
	Composition	Each Tablet Contains: Olmesartan Medoxomil……...…….20 mg Amlodipine……...10 mg
	Diary No. Date of R & I & fee	Dy. No 12082 dated 06-03-2019; Rs.20,000/- dated 27-02-2019.
	Pharmacological Group	Calcium Ion influx inhibitor, Antihypertensive.
	Type of Form	Form – 5
	Finished product Specification	Not provided (USP)
	Pack size & Demanded Price	Not Provided
	Approval status of product in Reference Regulatory Authorities	Azor 20mg/10mg film coated tablet, Daiichi-Sankyo UK ltd. UK(USFDA)
	Me-too status	Olmedip 10mg/20mg tablet by Shrooq Pharmaceuticals, Lahore.Reg. No. 068082.
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years.

		• Master formulation mentions film coating material, whereas Form-5 label claim doses not mention film coating dosage form. Which needs correction. • Form-5 label claim mentioned Amlodipine 10 mg where as master formulation mentioned Amlodipine besylate 10 mg, which need correction. • Finished Product testing specification not provided. • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size not provided.
	Decision: Deferred for following shortcomings: • **GMP certificate/inspection conducted within last 3 years.** • **Master formulation mentions film coating material, whereas Form-5 label claim doses not mention film coating dosage form. Which needs correction.** • **Form-5 label claim mentioned Amlodipine 10 mg where as master formulation mentioned Amlodipine besylate 10 mg, which need correction.** • **Finished Product testing specification not provided.** • **DML renewal status from CLB.** • **Section Approval letter form CLB.** • **Pack size not provided.**	
635.	Name and address of manufacturer/ Applicant	Baxter Pharmaceuticals (Pvt.) Ltd., A-1/A Scheme 33, Phase 1, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	PINEX-V Tablet 10/160 mg
	Composition	Each Tablet Contains: Amlodipine……...10 mg Valsartan……160 mg
	Diary No. Date of R & I & fee	Dy. No 12085 dated 06-03-2019; Rs.20,000/- dated 27-02-2019.
	Pharmacological Group	Calcium Ion influx inhibitor, Angiotensin II receptor blocker.
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	Not Provided
	Approval status of product in Reference Regulatory Authorities	Exforge film-coated tablet 10/160. USFDA approved
	Me-too status	VALTAN -M 170 PLUS TABLET. Reg. No. 77207
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Master formulation mentions film coating material, whereas Form-5 label claim doses not mention film coating dosage form. Which needs correction. • Form-5 label claim mentioned Amlodipine 10 mg where as master formulation mentioned Amlodipine besylate 10 mg, which need correction. • Finished Product testing specification not provided. • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size not provided.
	Decision: Deferred for following shortcomings: • **GMP certificate/inspection conducted within last 3 years.** • **Master formulation mentions film coating material, whereas Form-5 label claim doses not mention film coating dosage form. Which needs correction.** • **Form-5 label claim mentioned Amlodipine 10 mg where as master formulation mentioned Amlodipine besylate 10 mg, which need correction.** • **Finished Product testing specification not provided.** • **DML renewal status from CLB.** • **Section Approval letter form CLB.** • **Pack size not provided.**	

636.	Name and address of manufacturer/ Applicant	Baxter Pharmaceuticals (Pvt.) Ltd., A-1/A Scheme 33, Phase 1, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	VASORIL Tablet 20 mg
	Composition	Each Tablet Contains: Nicorandil…….20 mg
	Diary No. Date of R & I & fee	Dy. No 12114 dated 06-03-2019; Rs.20,000/- dated 27-02-2019.
	Pharmacological Group	Potassium Channel Activator
	Type of Form	Form – 5
	Finished product Specification	Not provided (BP)
	Pack size & Demanded Price	Not Provided
	Approval status of product in Reference Regulatory Authorities	Ikorel MHRA Approved.
	Me-too status	058054Ikodil 20mg Tablet of M/s OBS Pakistan (Pvt) Ltd,
	GMP status	Not provided within last 3 years
	Remarks of the Evaluator	• GMP certificate/inspection conducted within last 3 years. • Finished Product testing specification not provided. • DML renewal status from CLB. • Section Approval letter form CLB. • Pack size not provided.
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within last three years.** • **Finished Product testing specification not provided.** • **Pack size not provided.**	
637.	Name and address of manufacturer/ Applicant	Getz Pharma (Pvt.) Ltd., 29-30, Sector-27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	VORTIGET Tablet 5 mg
	Composition	Each Film Coated Tablet Contains; Vortioxetine Hydrobromide eq. to Vortioxetine……5 mg
	Diary No. Date of R & I & fee	Dy. No 12726 dated 06-03-2019; Rs.50,000/- dated 05-03-2019.
	Pharmacological Group	Antidepressant
	Type of Form	Form – 5D
	Finished product Specification	Manufacturer Specification's
	Pack size & Demanded Price	14's Rs: 1125 & 28s Rs:2250.
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	
	GMP status	Last GMP certificate is issued on 24-02-2019 based on inspection conducted on 07-01-2019 valid for 3 years.
	Remarks of the Evaluator	• Stability study data as per the guidelines approved in 293rd meeting of Registration Board. • GMP certificate/inspection conducted within last 3 years.
	Decision: Deferred for submission and evaluation of Stability study data as per the guidelines approved in 293rd meeting of Registration Board on their turn .	
638.	Name and address of manufacturer/ Applicant	Getz Pharma (Pvt.) Ltd., 29-30, Sector-27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	VORTIGET Tablet 10 mg
	Composition	Each Film Coated Tablet Contains; Vortioxetine Hydrobromide eq. to Vortioxetine…10 mg
	Diary No. Date of R & I & fee	Dy. No 12727 dated 06-03-2019; Rs.50,000/- dated 05-03-2019.
	Pharmacological Group	Antidepressant
	Type of Form	Form – 5D
	Finished product Specification	Manufacturer Specification's
	Pack size & Demanded Price	14's Rs: 1250 & 28s Rs:2500.

	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	
	GMP status	Last GMP certificate is issued on 24-02-2019 based on inspection conducted on 07-01-2019 valid for 3 years.
	Remarks of the Evaluator	• Stability study data as per the guidelines approved in 293rd meeting of Registration Board. • GMP certificate/inspection conducted within last 3 years.
	Decision: Deferred for submission and evaluation of Stability study data as per the guidelines approved in 293rd meeting of Registration Board on their turn .	
639.	Name and address of manufacturer/ Applicant	Getz Pharma (Pvt.) Ltd., 29-30, Sector-27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	VORTIGET Tablet 15 mg
	Composition	Each Film Coated Tablet Contains; Vortioxetine Hydrobromide eq. to Vortioxetine…15 mg
	Diary No. Date of R & I & fee	Dy. No 12728 dated 06-03-2019; Rs.50,000/- dated 05-03-2019.
	Pharmacological Group	Antidepressant
	Type of Form	Form – 5D
	Finished product Specification	Manufacturer Specification's
	Pack size & Demanded Price	14's Rs: 1375 & 28s Rs:2750.
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	
	GMP status	Last GMP certificate is issued on 24-02-2019 based on inspection conducted on 07-01-2019 valid for 3 years.
	Remarks of the Evaluator	• Stability study data as per the guidelines approved in 293rd meeting of Registration Board. • GMP certificate/inspection conducted within last 3 years.
	Decision: Deferred for submission and evaluation of Stability study data as per the guidelines approved in 293rd meeting of Registration Board on their turn .	
640.	Name and address of manufacturer/ Applicant	Getz Pharma (Pvt.) Ltd., 29-30, Sector-27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	VORTIGET Tablet 20 mg
	Composition	Each Film Coated Tablet Contains; Vortioxetine Hydrobromide eq. to Vortioxetine…20 mg
	Diary No. Date of R & I & fee	Dy. No 12729 dated 06-03-2019; Rs.50,000/- dated 05-03-2019.
	Pharmacological Group	Antidepressant
	Type of Form	Form – 5D
	Finished product Specification	Manufacturer Specification's
	Pack size & Demanded Price	14's Rs: 1500 & 28s Rs:3000
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	
	GMP status	Last GMP certificate is issued on 24-02-2019 based on inspection conducted on 07-01-2019 valid for 3 years.
	Remarks of the Evaluator	• Stability study data as per the guidelines approved in 293rd meeting of Registration Board. • GMP certificate/inspection conducted within last 3 years.
	Decision: Deferred for submission and evaluation of Stability study data as per the guidelines approved in 293rd meeting of Registration Board on their turn .	
641.	Name and address of manufacturer/ Applicant	PharmEVO (Pvt.) Ltd. A-29,North Industrial Zone,Port Qasim,Karachi.
	Brand Name + Dosage Form + Strength	LESIRINOL Tablet 200/300 mg

	Composition	Each Film Coated Tablet Contains; Lesinurad……...200 mg Allopurinol……300 mg
	Diary No. Date of R & I & fee	Dy. No. 12303 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Uric Acid reabsorption Inhibitor, Xanthine oxidase Inhibitor.
	Type of Form	Form – 5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	7's,10's,14's,20's,28's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued.
	Me-too status	
	GMP status	Last GMP inspection was conducted on 23-02-2018 concluding acceptable level of GMP compliance.
	Remarks of the Evaluator	• Stability study data as per the guidelines approved in 293rd meeting of Registration Board. • GMP certificate/inspection conducted within last 3 years. • The product status in USFDA is discontinued, provide valid RRA reference for international availability.
	Decision: deferred for following shortcomings: **• Submission of Stability study data as per the guidelines approved in 293rd meeting of Registration Board.** **• GMP certificate/inspection conducted within last 3 years.** **• The product status in USFDA is discontinued, provide valid RRA reference .**	
642.	Name and address of manufacturer/ Applicant	PharmEVO (Pvt.) Ltd. A-29, North Industrial Zone, Port Qasim,Karachi.
	Brand Name + Dosage Form + Strength	LESIRINOL Tablet 200/200 mg
	Composition	Each Film Coated Tablet Contains; Lesinurad……...200 mg Allopurinol……200 mg
	Diary No. Date of R & I & fee	Dy. No. 12302 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Uric Acid reabsorption Inhibitor, Xanthine oxidase Inhibitor.
	Type of Form	Form – 5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	7's,10's,14's,20's,28's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued
	Me-too status	
	GMP status	Last GMP inspection was conducted on 23-02-2018 concluding acceptable level of GMP compliance.
	Remarks of the Evaluator	• Stability study data as per the guidelines approved in 293rd meeting of Registration Board. • GMP certificate/inspection conducted within last 3 years. • The product status in USFDA is discontinued, provide valid RRA reference for international availability.
	Decision: deferred for following shortcomings: **• Submission of Stability study data as per the guidelines approved in 293rd meeting of Registration Board.** **• GMP certificate/inspection conducted within last 3 years.** **• The product status in USFDA is discontinued, provide valid RRA reference .**	
643.	Name and address of manufacturer/ Applicant	PharmEVO (Pvt.) Ltd. A-29, North Industrial Zone, Port Qasim,Karachi.
	Brand Name + Dosage Form + Strength	DAPAMET XR 5/1000 mg
	Composition	Each Film Coated Tablet Contains;

		Dapagliflozin propanediol Monohydrate eq to Dapagliflozin …….....5mg Metformin HCl……1000 mg
	Diary No. Date of R & I & fee	Dy. No. 12299 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Reversible Competitive SGLT2 Inhibitor, Anti Hyperglycemic
	Type of Form	Form – 5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	7's,10's,14's,20's,28's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	USFDA approved, XIGDUO XR , Extended release Tablet.
	Me-too status	-
	GMP status	Last GMP inspection was conducted on 23-02-2018 concluding acceptable level of GMP compliance.
	Remarks of the Evaluator	• Stability study data as per the guidelines approved in 293rd meeting of Registration Board. • GMP certificate/inspection conducted within last 3 years. • Label Claim does not mention extended release dosage form which needs clarification.
	Decision: deferred for following shortcomings: **• Submission of Stability study data as per the guidelines approved in 293rd meeting of Registration Board.** **• GMP certificate/inspection conducted within last 3 years.** **• Label Claim does not mention extended release dosage form which needs clarification.**	
644.	Name and address of manufacturer/ Applicant	PharmEVO (Pvt.) Ltd. A-29, North Industrial Zone, Port Qasim,Karachi.
	Brand Name + Dosage Form + Strength	DAPAMET XR 10/1000 mg
	Composition	Each Film Coated Tablet Contains; Dapagliflozin propanediol Monohydrate eq to Dapagliflozin …….....10mg Metformin HCl……1000 mg
	Diary No. Date of R & I & fee	Dy. No. 12301 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Reversible Competitive SGLT2 Inhibitor, Anti Hyperglycemic
	Type of Form	Form – 5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	7's,10's,14's,20's,28's,30's, As per DPC
	Approval status of product in Reference Regulatory Authorities	USFDA approved, XIGDUO XR , Extended release Tablet.
	Me-too status	
	GMP status	Last GMP inspection was conducted on 23-02-2018 concluding acceptable level of GMP compliance.
	Remarks of the Evaluator	• Stability study data as per the guidelines approved in 293rd meeting of Registration Board. • GMP certificate/inspection conducted within last 3 years. • Label Claim does not mention extended release dosage form which needs clarification.
	Decision: deferred for following shortcomings: **• Submission of Stability study data as per the guidelines approved in 293rd meeting of Registration Board.** **• GMP certificate/inspection conducted within last 3 years.** **• Label Claim does not mention extended release dosage form which needs clarification.**	
645.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.
	Brand Name + Dosage Form + Strength	DELAS Capsule 30 mg

	Composition	Each Capsule Contains: Dexlansoprazole (Enteric Coated pellets) ……30 mg	
	Diary No. Date of R & I & fee	Dy. No 12584 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Proton Pump Inhibitor	
	Type of Form	Form – 5	
	Finished product Specification	Manufacturer specification	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA, Dexilant Capsule	
	Me-too status	Razodex of Getz Pharma	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Complete manufacturing out line. • Complete finished product testing specification. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Source of pellets with GMP, COA and stability study of pellets • Pack size.	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Deferred for submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board is required along with source of pellets (Source approval Fee in case of foreign source of pellets)		
646.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	C-THROCIN Tablet 500 mg	
	Composition	Each Film Coated Tablet Contains: Clarithromycin…….500 mg	
	Diary No. Date of R & I & fee	Dy. No 12604 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Quinolone Antibiotic	
	Type of Form	Form – 5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	MHRA Approved	
	Me-too status	Clarital 500mg tablet of M/s Arsons Pharma, Lahore 085500	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete manufacturing out line.	Firm has submitted reply along with, master formulation, outline of manufacturing Method and GMP certificate.

		• Complete finished product testing specifications.	
	Decision:Approved with USP specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
647.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	APRANT Capsule (Combo Pack)	
	Composition	Each Combo Pack Contains: 2 Capsule of Aprepitant Aprepitant ……80mg 1 Capsule of Aprepitant Aprepitant……125mg	
	Diary No. Date of R & I & fee	Dy. No 12597 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antiemetic	
	Type of Form	Form – 5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	Combo Pack (Aprepitant 80 mg ,2 Cap & Aprepitant 125 mg ,1 Cap), As per DPC	
	Approval status of product in Reference Regulatory Authorities	USFDA Approved. EMEND® 125 mg hard capsules, EMEND® 80 mg hard capsules. Aluminium blister containing one 125mg capsule and two 80mg capsules	
	Me-too status	Apreon Combo Pack Capsules of M/S Ferozesons Labs,. Reg. No. 068204	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete manufacturing out line mentioning combo pack manufacturing and packaging method. • Complete finished product testing specifications.	Firm has submitted reply along with, master formulation, outline of manufacturing Method and GMP certificate.
	Decision:Deferred for confirmation of required manufacturing facility/equipment for Combo Packaging.		
648.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	LINZO Suspension (Dry Powder)	
	Composition	Each 5 ml Contain: (After reconstitution) Linezolid…….100 mg	
	Diary No. Date of R & I & fee	Dy. No 12624 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antibacterial	
	Type of Form	Form – 5	
	Finished product Specification	Not provided	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	ZYVOX (100mg/5ml) for oral suspension USFDA Approved	
	Me-too status	Nezo 100mg/5ml Dry Suspension by M/s Rotex Pharma (Reg#097440)	

	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Manufacturing method of liquid syrup provided where as label claim is granular powder for suspension. Provide revised manufacturing out line. • Complete finished product testing specifications.	Firm has submitted reply along with, master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Approved with innovator's specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
649.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	ORLIT Capsule	
	Composition	Each Capsule Contains: Orlistat IR Pellets 50% Eq .to Orlistat……120 mg (Source of pellets: M/s Vision Pharmaceuticals, Islamabad.)	
	Diary No. Date of R & I & fee	Dy. No 12583 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Not mentioned.	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / USP	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK	
	Me-too status	Orlovit capsules by M/s CCL Pharma (Reg.#046324)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Manufacturing method of powder Capsule is provided where as label claim is capsule containing pellets. • Provide revised manufacturing out line. • Complete finished product testing specifications. (usp) • COA of pellets, Stability Study of pellets, GMP of Source of pellets.	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		

650.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	CLOMI Tablet 50 mg	
	Composition	Each Tablet Contains: Clomiphene Citrate …….50 mg	
	Diary No. Date of R & I & fee	Dy. No 12605 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anti-Oestrogen	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / USP	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Clomid 50mg Tablets MHRA Approved as uncoated tablet.	
	Me-too status	Clomidex Tablets 50mg by CSH Pharmaceuticals-North (Reg#078433)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete Manufacturing outline. • Complete finished product testing specifications. (USP)	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Registration Board approved registration of product with USP specification ,in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. **The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012-B&A/DRAP dated 13-07-2021**		
651.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	FEBSTAT Tablet 80 mg	
	Composition	Each Film Coated Tablet Contains: Febuxostat …….80 mg	
	Diary No. Date of R & I & fee	Dy. No 12615 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antigout preparation	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/ Innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	ULORIC (40mg, 80mg) film coated tablets USFDA Approved	
	Me-too status	Febuxin 80mg tablet by AGP Ltd (Reg. 081105)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete Manufacturing outline. • Complete finished product testing	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.

		specifications. (Innovator)	
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
652.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	ACTIN Capsule 10 mg	
	Composition	Each Capsule Contains: Acitretin ……10 mg	
	Diary No. Date of R & I & fee	Dy. No 12595 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antipsoriatics	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/USP	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	NEOTIGASON acitretin 10mg capsule by M/s Teva Pharma Australia Pty Ltd (TGA Approved)	
	Me-too status	Acetin Capsules 10mg by M/s Genome Pharmaceuticals (Reg#064012)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete Manufacturing outline. • Complete finished product testing specifications. (USP)	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Approved with USP specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
653.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	ONDRON Syrup	
	Composition	Each 5 ml Contains: Ondansetron (as Hcl) ……4mg	
	Diary No. Date of R & I & fee	Dy. No 12627 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Selective 5-HT3 Receptor Antagonist (Antiemetic)	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Zofran solution 4mg/5ml, USFDA Approved,	
	Me-too status	Dantron Syrup of M/s Sharooq Pharma Reg No. 077076	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete finished product testing specifications. (Innovator)	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.

	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
654.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	MOXAFOS Capsule 500 mg	
	Composition	Each Capsule Contains: Fosfomycin Calcium eq to Fosfomycin……500 mg	
	Diary No. Date of R & I & fee	Dy. No 12616 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anti-Bacterial	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Calcium Fosfomycin Solufos 500 mg hard capsules. CIMA approved	
	Me-too status	Cynfo 500mg Capsule. Reg. No. 73702	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G), Capsule (G), Dry Powder Suspension (G), Liquid (G), and Sachet (G).	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete Manufacturing outline. • Complete finished product testing specifications.	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
655.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	MOXAFOS Sachet	
	Composition	Each Sachet Contains: Fosfomycin Trometamol eq to Fosfomycin……...3 gm	
	Diary No. Date of R & I & fee	Dy. No 12590 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Anti-Bacterial	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/ Innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Berny 3g granules for oral solution MHRA approved	
	Me-too status	Monufos 3g Oral Sachet by M/s Rotex Pharma (Reg#097453)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G), Capsule (G), Dry Powder Suspension (G), Liquid (G), and Sachet (G).	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete Manufacturing outline. • Complete finished product testing specifications. (innovator)	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.

	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
656.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	VOMGYNE Tablet	
	Composition	Each Enteric Coated Delayed Release Tablet Contains: Doxylamine Succinate……10 mg Pyridoxine HCl……...10 mg	
	Diary No. Date of R & I & fee	Dy. No 12612 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antihistamine, Vitamin B6	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Doxylamine Succinate And Pyridoxine Hydrochloride (10/10) | ANDA #205811 | Tablet, Delayed Release;Oral | Prescription | Actavis Labs Fl Inc. Approved in USFDA	
	Me-too status	Femiroz Tablet by M/s Efroze (Reg#061026)	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete Manufacturing outline for dual release enteric coated tablet. • Complete finished product testing specifications. (innovator)	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
657.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	ERDINE Sachet 225 mg	
	Composition	Each Sachet Contains: Erdosteine……225 mg	
	Diary No. Date of R & I & fee	Dy. No 12613 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	AntiFungal	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/Innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	AIFA Italy, ESTECLIN Sachet,	
	Me-too status	Mucolec 225 mg Sachet of M/s Wnsfeild Pharmaceutical, Industrial Estate, Hattar 078593	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G), Capsule (G), Dry Powder Suspension (G), Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management.	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.

		• Complete finished product testing specifications. • Pack size	
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
658.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	LEXATIVE Sachet	
	Composition	Each Sachet Contains: Macrogol 3350……..……..13.125 g Sodium Chloride……..…0.3507 g Sodium Bicarbonate……0.1785 g Potassium Chloride……..…0.0466 g	
	Diary No. Date of R & I & fee	Dy. No 12630 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antacid	
	Type of Form	Form – 5	
	Finished product Specification	Not provided / Innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Movicol 13.8g sachet, powder for oral solution. Approved by MHRA	
	Me-too status	Forlax Sachet. Reg. No. 82099	
	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete Manufacturing outline. • Complete finished product testing specifications. (innovator) • Pack/sachet contents net weight is not mentioned in label claim.	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
659.	Name and address of manufacturer/ Applicant	Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd.TBIC building-1, PCSIR Laboratories complex, Karachi.	
	Brand Name + Dosage Form + Strength	RENISCON PLUS Syrup	
	Composition	Each 10 ml Contains: Sodium Alginate……..…1000 mg Potassium Hydrogen Carbonate……200 mg	
	Diary No. Date of R & I & fee	Dy. No 12617 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Antacid	
	Type of Form	Form – 5	
	Finished product Specification	Not provided/innovator	
	Pack size & Demanded Price	As per DPC	
	Approval status of product in Reference Regulatory Authorities	Gaviscon Advance Oral suspension 1000mg/200mg per 10ml by M/s Reckitt Benckiser Healthcare (UK) Ltd, MHRA Approved	
	Me-too status	Gesecon Advance 1000/200 syrup by M/s Winthrox Karachi, Reg. No. 74951	

	GMP status	GMP certificate issued dated 31-12-2021 on the basis of inspection conducted on 11-11-2021 for Tablet (G),Capsule (G) , Dry Powder Suspension (G) , Liquid (G) , and Sachet (G) .	
	Remarks of the Evaluator	• Master Formulation. • Form-5 not signed by firm management. • Complete Manufacturing outline. • Complete finished product testing specifications. (Innovator Spec)	Firm has submitted reply along with master formulation, outline of manufacturing Method and GMP certificate.
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
660.	Name and address of manufacturer/ Applicant	Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road) Lahore.	
	Brand Name + Dosage Form + Strength	BACKALEN Capsule 100 mg	
	Composition	Each Capsule Contains: Pregabalin…….100 mg	
	Diary No. Date of R & I & fee	Dy. No 12525 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Anticonvulsant /GABA analogue	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer specification	
	Pack size & Demanded Price	14's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Lyrica capsule 100mg by M/s Pfizer, USFDA Approved.	
	Me-too status	Zeegap Capsule 100mg by M/s Hilton Pharma,047360	
	GMP status	Firm was granted GMP certificate dated 14-12-2021on the basis of GMP inspection conducted on 11-06-2021 for Tablet (General) & (Psychotropic), Capsule (General) &(Cephalosporin), Oral Dry Powder Suspension (Ceph), Dry Powder Injection (Ceph), Liquid Injection Ampoule (General) & Liquid Ampoule (General)	
	Remarks of the Evaluator		
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
661.	Name and address of manufacturer/ Applicant	Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road) Lahore.	
	Brand Name + Dosage Form + Strength	BACKALEN Capsule 300 mg	
	Composition	Each Capsule Contains: Pregabalin…….300 mg	
	Diary No. Date of R & I & fee	Dy. No 12527 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Anticonvulsant /GABA analogue	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer specification	
	Pack size & Demanded Price	14's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg,300mg) Capsules, USFDA Approved	
	Me-too status	Gabica 300mg Capsules, Getz Pharma, Reg. No. 047368.	
	GMP status	Firm was granted GMP certificate dated 14-12-2021on the basis of GMP inspection conducted on 11-06-2021 for Tablet (General) & (Psychotropic), Capsule (General) &(Cephalosporin), Oral Dry Powder Suspension (Ceph), Dry Powder Injection (Ceph), Liquid Injection Ampoule (General) & Liquid Ampoule (General)	
	Remarks of the Evaluator		

	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
662.	Name and address of manufacturer/ Applicant	Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road) Lahore.
	Brand Name + Dosage Form + Strength	BACKALEN Capsule 150 mg
	Composition	Each Capsule Contains: Pregabalin…….150 mg
	Diary No. Date of R & I & fee	Dy. No 12526 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Anticonvulsant /GABA analogue
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's, As per DPC
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg,300mg) Capsules, USFDA Approved
	Me-too status	Gabica 150mg Capsules by M/s Getz Pharma (Reg#48724)
	GMP status	Firm was granted GMP certificate dated 14-12-2021on the basis of GMP inspection conducted on 11-06-2021 for Tablet (General) & (Psychotropic), Capsule (General) &(Cephalosporin), Oral Dry Powder Suspension (Ceph), Dry Powder Injection (Ceph), Liquid Injection Ampoule (General) & Liquid Ampoule (General)
	Remarks of the Evaluator	
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
663.	Name and address of manufacturer/ Applicant	Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road) Lahore.
	Brand Name + Dosage Form + Strength	BACKALEN Capsule 75 mg
	Composition	Each Capsule Contains: Pregabalin…….75 mg
	Diary No. Date of R & I & fee	Dy. No 12524 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Anticonvulsant /GABA analogue
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's, As per DPC
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg,300mg) Capsules, USFDA Approved
	Me-too status	Zeegap Capsule 75mg by M/s Hilton Pharma, Reg. No. 047359
	GMP status	Firm was granted GMP certificate dated 14-12-2021on the basis of GMP inspection conducted on 11-06-2021 for Tablet (General) & (Psychotropic), Capsule (General) &(Cephalosporin), Oral Dry Powder Suspension (Ceph), Dry Powder Injection (Ceph), Liquid Injection Ampoule (General) & Liquid Ampoule (General)
	Remarks of the Evaluator	
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
664.	Name and address of manufacturer/ Applicant	Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road) Lahore.
	Brand Name + Dosage Form + Strength	PECOLEP Tablet 100 mg
	Composition	Each Film Coated Tablet Contains: Lacosamide ……100 mg
	Diary No. Date of R & I & fee	Dy. No 12521 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antiepileptic/ Sodium Channel Inactivator
	Type of Form	Form-5

	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's, As per DPC
	Approval status of product in Reference Regulatory Authorities	MHRA Approved film coated 100 mg tablet, Torrent Pharma,UK.
	Me-too status	Lacogit-100 100mg Tablets, Reg # 083580, Glitz Pharma, Islamabad.
	GMP status	Firm was granted GMP certificate dated 14-12-2021on the basis of GMP inspection conducted on 11-06-2021 for Tablet (General) & (Psychotropic), Capsule (General) &(Cephalosporin), Oral Dry Powder Suspension (Ceph), Dry Powder Injection (Ceph), Liquid Injection Ampoule (General) & Liquid Ampoule (General)
	Remarks of the Evaluator	
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
665.	Name and address of manufacturer/ Applicant	Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road) Lahore.
	Brand Name + Dosage Form + Strength	PECOLEP Tablet 150 mg
	Composition	Each Film Coated Tablet Contains: Lacosamide ……150 mg
	Diary No. Date of R & I & fee	Dy. No 12522 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antiepileptic/ Sodium Channel Inactivator
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's, As per DPC
	Approval status of product in Reference Regulatory Authorities	VIMPAT (50mg, 100mg, 150mg, 200mg) film coated tablet USFDA approved.
	Me-too status	Atcomid 150mg Tablet M/s Atco Lab
	GMP status	Firm was granted GMP certificate dated 14-12-2021on the basis of GMP inspection conducted on 11-06-2021 for Tablet (General) & (Psychotropic), Capsule (General) &(Cephalosporin), Oral Dry Powder Suspension (Ceph), Dry Powder Injection (Ceph), Liquid Injection Ampoule (General) & Liquid Ampoule (General)
	Remarks of the Evaluator	
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
666.	Name and address of manufacturer/ Applicant	Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road) Lahore.
	Brand Name + Dosage Form + Strength	PECOLEP Tablet 50 mg
	Composition	Each Film Coated Tablet Contains: Lacosamide ……50 mg
	Diary No. Date of R & I & fee	Dy. No 12515 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antiepileptic/ Sodium Channel Inactivator
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Lacosamide Aspire 50 mg film-coated tablets by Aspire Pharma Limited. MHRA Approved.
	Me-too status	Lalap 50mg tablet. Reg. No. 70470
	GMP status	Firm was granted GMP certificate dated 14-12-2021on the basis of GMP inspection conducted on 11-06-2021 for Tablet (General) & (Psychotropic), Capsule (General) &(Cephalosporin), Oral Dry Powder Suspension (Ceph), Dry Powder Injection (Ceph), Liquid Injection Ampoule (General) & Liquid Ampoule (General)
	Remarks of the Evaluator	

	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
667.	Name and address of manufacturer/ Applicant	Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road) Lahore.	
	Brand Name + Dosage Form + Strength	PECOLEP Tablet 200 mg	
	Composition	Each Film Coated Tablet Contains: Lacosamide ……200 mg	
	Diary No. Date of R & I & fee	Dy. No 12523 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antiepileptic/ Sodium Channel Inactivator	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer specification	
	Pack size & Demanded Price	14's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	VIMPAT (50mg, 100mg, 150mg, 200mg) film coated tablet USFDA approved.	
	Me-too status	Lacolit 200mg Tablet by M/s The Searle Company Limited,(Reg#077125)	
	GMP status	Firm was granted GMP certificate dated 14-12-2021on the basis of GMP inspection conducted on 11-06-2021 for Tablet (General) & (Psychotropic), Capsule (General) &(Cephalosporin), Oral Dry Powder Suspension (Ceph), Dry Powder Injection (Ceph), Liquid Injection Ampoule (General) & Liquid Ampoule (General)	
	Remarks of the Evaluator		
	Decision: Approved with innovator specifications. The firm shall submit preregistration variation fee of 7500/= as per SRO. No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
668.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	DABROXOL Capsule 50 mg	
	Composition	Each Capsule Contains: Dabrafenib…….50 mg	
	Diary No. Date of R & I & fee	Dy. No 12753 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Inhibitor of BRAF Kinases	
	Type of Form	Form-5	
	Finished product Specification	innovator Specifications	
	Pack size & Demanded Price	28's,120's	
	Approval status of product in Reference Regulatory Authorities	Tafinlar capsule (50mg & 75mg) by M/s Novartis, USFDA Approved.	
	Me-too status	Not Confirmed.	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator	• The reference product contains Dabrafenib (as mesylate) …… 50mg. • Evidence of applied formulation/drug already approved by DRAP (generic / me-	Firm has submitted reply with fee challan No 18869751112 dated 21-07-2022 of 7500/= along with revised Form -5 mention revised label claim as under: Each capsule Contains:

		too status) along with registration number, brand name and name of firm.	Dabrafenib as mesylate……50 mg (Pharmasol Spec.)
	Decision: Deferred for • **Submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board**		
669.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	DABROXOL Capsule 75 mg	
	Composition	Each Capsule Contains: Dabrafenib…….75 mg	
	Diary No. Date of R & I & fee	Dy. No 12754 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Inhibitor of BRAF Kinases	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer Specifications	
	Pack size & Demanded Price	28's,120's	
	Approval status of product in Reference Regulatory Authorities	Tafinlar capsule (50mg & 75mg) by M/s Novartis, USFDA Approved.	
	Me-too status	Not Confirmed.	
	GMP status	The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations: "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator	• The reference product contains Dabrafenib (as mesylate) …… 75 mg. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm	Firm has submitted reply with fee challan No .90660622 dated 21-07-2022 along with revised Form -5 mention revised label claim as under: Each capsule Contains: Dabrafenib as mesylate……75 mg (Pharmasol Specs.).
	Decision: Deferred for • **Submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.**		
670.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	ZIPSOL Capsule 20 mg	
	Composition	Each Capsule Contains: Ziprasidone (As Hydrochloride Monohydrate) …….20mg	
	Diary No. Date of R & I & fee	Dy. No 12737 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Dopamine D2 and Serotonin 5HT2 antagonist	
	Type of Form	Form-5	

	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's,28's,30's
	Approval status of product in Reference Regulatory Authorities	Geodon capsule (20mg, 40mg, 60mg, 80mg) by M/s Pfizer, USFDA Approved.
	Me-too status	Xavidone 20mg Capsule, 103335, Genetics Pharmaceuticals (Pvt) Ltd,Lahore
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	Firm has submitted copy of GMP certificate upon inspection conducted on 22-08-2022.
	Decision: Approved.	
671.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	ZIPSOL Capsule 40 mg
	Composition	Each Capsule Contains: Ziprasidone (As Hydrochloride Monohydrate) …….40mg
	Diary No. Date of R & I & fee	Dy. No 12738 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Dopamine D2 and Serotanin 5HT2 antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's,28's,30's
	Approval status of product in Reference Regulatory Authorities	Geodon capsule (20mg, 40mg, 60mg, 80mg) by M/s Pfizer, USFDA Approved.
	Me-too status	Xavidone 40mg Capsule, 103336, Genetics Pharmaceuticals (Pvt) Ltd,Pakistan
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	Firm has submitted copy of GMP certificate upon inspection conducted on 22-08-2022.
	Decision: Approved.	
672.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	BISCORD-H Tablet 5 /6.25 mg
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate …….5 mg Hydrochlorothiazide……6.25 mg
	Diary No. Date of R & I & fee	Dy. No 12732 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5

	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's,28's,30's
	Approval status of product in Reference Regulatory Authorities	Ziac Tablets by Teva Pharms (USFDA Approved)
	Me-too status	Actim-H by Sami
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	Firm has submitted copy of GMP certificate upon inspection conducted on 22-08-2022.
	Decision: Approved.	
673.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	BISCORD-H Tablet 2.5 /6.25 mg
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate …….2.5 mg Hydrochlorothiazide……6.25 mg
	Diary No. Date of R & I & fee	Dy. No 12731 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's,28's,30's
	Approval status of product in Reference Regulatory Authorities	Ziac Tablets by Teva Pharms (USFDA Approved)
	Me-too status	Lodoz Tablets Each Film Coated Tablet Contains: - Bisoprolol Fumarate……2.5mg Hydrochlorothiazide…….6.25mg Reg # 025583, Merck Pvt Ltd., 7, Jail Road, Quetta.
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	Firm has submitted copy of GMP certificate upon inspection conducted on 22-08-2022.
	Decision: Approved.	
674.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	BISCORD-H Tablet 10 /12.5 mg
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate ……...10 mg Hydrochlorothiazide……12.5 mg
	Diary No. Date of R & I & fee	Dy. No 12734 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.

	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14,20's,28's,30's
	Approval status of product in Reference Regulatory Authorities	Ziac Tablets by Teva Pharms (USFDA Approved)
	Me-too status	Actim-H by Sami
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	Firm has submitted copy of GMP certificate upon inspection conducted on 22-08-2022.
	Decision: Approved.	
675.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	ROXONIB Tablet 15 mg
	Composition	Each Tablet Contains: Ruxolitinib as Phosphate……15 mg
	Diary No. Date of R & I & fee	Dy. No 12769 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Selective Inhibitor of the Janus Associated Kinases (JAKs)
	Type of Form	Form-5
	Finished product Specification	Innovator specifcations
	Pack size & Demanded Price	10's,20's,56's,60's.
	Approval status of product in Reference Regulatory Authorities	Jakavi® 15 mg tablets, MHRA approved.
	Me-too status	Ruxonib 15mg Tablet, 101690, Rotex Pharma (Pvt) Ltd.,Pakistan
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved	
676.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	ROXONIB Tablet 5 mg
	Composition	Each Tablet Contains: Ruxolitinib as Phosphate……5 mg
	Diary No. Date of R & I & fee	Dy. No 12768 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Selective Inhibitor of the Janus Associated Kinases (JAKs)

	Type of Form	Form-5
	Finished product Specification	innovator specification
	Pack size & Demanded Price	10's,20's,56's,60's.
	Approval status of product in Reference Regulatory Authorities	Jakavi® 5 mg tablets, MHRA approved
	Me-too status	Ruxonib 5mg Tablet, 101689, Rotex Pharma (Pvt) Ltd.Islamabad.
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved	
677.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	ELTROM Tablet 50 mg
	Composition	Each Film Coated Tablet Contains: Eltrombopag as Olamine……50mg
	Diary No. Date of R & I & fee	Dy. No 12772 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	TPO-receptor Agonist
	Type of Form	Form-5
	Finished product Specification	Innovator specification
	Pack size & Demanded Price	25's
	Approval status of product in Reference Regulatory Authorities	Revolade® 50 mg film-coated tablets, MHRA approved
	Me-too status	Revolade Tablet 50mg, 084159, Novartis Pharma (Pak) Ltd.,Karachi
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved	
678.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	ELTROM Tablet 25 mg
	Composition	Each Film Coated Tablet Contains: Eltrombopag as Olamine……25mg
	Diary No. Date of R & I & fee	Dy. No 12771 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	TPO-receptor Agonist
	Type of Form	Form-5
	Finished product Specification	Innovators specification
	Pack size & Demanded Price	25's

	Approval status of product in Reference Regulatory Authorities	Revolade® 25 mg film-coated tablets, MHRA approved
	Me-too status	Revolade Tablet 25mg, 084158, Novartis Pharma (Pak) Ltd., Karachi.
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved	
679.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	CYTOCARB Injection 500mg/5ml
	Composition	Each 5 ml Vial Contains: Cytarabine…….500 mg
	Diary No. Date of R & I & fee	Dy. No 12761 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antineoplastic
	Type of Form	Form-5
	Finished product Specification	BP specification
	Pack size & Demanded Price	1's
	Approval status of product in Reference Regulatory Authorities	ANSM approved.
	Me-too status	Cytu 500mg/5ml Solution for injection, 099018, Punjab Medical Services, Lahore (Importer)
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	Undertaking /commitment as approved in 245th meeting of DRB.
	Decision: Approved.	
680.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	CYTOCARB Injection 1gm/10ml
	Composition	Each 10 ml Vial Contains: Cytarabine…….1000 mg
	Diary No. Date of R & I & fee	Dy. No 12751 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antineoplastic
	Type of Form	Form-5
	Finished product Specification	BP specification
	Pack size & Demanded Price	1's
	Approval status of product in Reference Regulatory Authorities	CYTARABINE ACCORD 100 mg / ml, solution for injection or infusion of HEALTHCARE FRANCE SAS

		AGREEMENT,45 RUE DU FAUBOURG DE ROUBAIX 59000 LILLE(ANSM approved)	
	Me-too status	Cytabine Injection., 072596, Each 10ml vial contains Cytarabine: 1000mg, AJM Pharma (Pvt) Ltd., Plot No. 44 Sector 27 Korangi Industrial Area Karachi., Karachi	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator		
	Decision: Approved.		
681.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	LEUKORIN Injection 15mg/2ml	
	Composition	Each 2ml ampoule Contains: Folinic Acid as Calcium Folinate……15 mg	
	Diary No. Date of R & I & fee	Dy. No 12764 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Detoxifying agent for Antineoplastic Treatment	
	Type of Form	Form-5	
	Finished product Specification	USP specification (B.P)	
	Pack size & Demanded Price	1's,10's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	MHRA approved (15mg/2ml Injection)	
	Me-too status	Calco 15mg/2ml Injection, 097796, Rotex Pharma (Pvt) Ltd., Islamabad	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator	• Copy of claimed official finished product specification, i-e USP.	• Firm has submitted copy of USP monograph for Leucovorin Calcium Injection.
	Decision: Approved with USP specifications.		
682.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	LEUKORIN Injection 50mg/5ml	
	Composition	Each 5ml ampoule Contains: Folinic Acid as Calcium Folinate……50 mg	
	Diary No. Date of R & I & fee	Dy. No 12765 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Detoxifying agent for Antineoplastic Treatment, Vitamin	
	Type of Form	Form-5	

	Finished product Specification	USP specification (B.P)	
	Pack size & Demanded Price	1's,10's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	MHRA approved, 50 mg/5 ml (10 mg/ml) Injection.	
	Me-too status	Calco 50mg/5ml Injection, 097797, Rotex Pharma (Pvt) Ltd., Islamabad.	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator	Copy of claimed official finished product specification, i-e USP.	Firm has submitted copy of USP monograph for Leucovorin Calcium Injection.
	Decision: Approved		
683.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	OXALISOL Injection 100mg/20ml	
	Composition	Each 20 ml Vials Contains: Oxaliplatin……100 mg	
	Diary No. Date of R & I & fee	Dy. No 12749 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Selective inhibitor of DNA synthesis	
	Type of Form	Form-5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	1's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	MHRA approved as concentrate for solution for Infusion. 50 mg/10 ml (5mg/ml) and 100 mg/20 ml	
	Me-too status	Oxaliplatin "Ebewe" 100mg /20ml – Concentrate For Solution For Infusion. 081776, Novartis Pharma (Pak) Ltd. Karachi	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator	• Master Formulation mentioned "Lactose Mono hydrate as Lyophilization Aid. "whereas per label claim the product is Liquid Injection which needs clarification and revision of formulation.	• Firm has submitted reply with challan fee No.60945157521 dated 21-07-2022 of 7500/= along with revised master formulation as liquid Injection .

	Decision: Approved		
684.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	OXALISOL Injection 50mg/10ml	
	Composition	Each 10 ml Vials Contains: Oxaliplatin……..…50 mg	
	Diary No. Date of R & I & fee	Dy. No 12762 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Selective inhibitor of DNA synthesis	
	Type of Form	Form-5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	1's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	MHRA approved as concentrate for solution for Infusion. 50 mg/10 ml (5mg/ml) and 100 mg/20 ml	
	Me-too status	ELOXATIN 50mg per vial injection by M/S SANOFI AVENTIS PAKISTAN LIMITED	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator	• Master Formulation mentioned "Lactose Mono hydrate as Lyophilization Aid". Whereas per label claim the product is Liquid Injection which needs clarification and revision of formulation.	• Firm has submitted reply with challan fee No.399578222 dated 21-07-2022 of 7500/= along with revised master formulation as liquid Injection .
	Decision: Approved.		
685.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	GLYNIB Tablet 400 mg	
	Composition	Each Film Coated Tablet Contains: Imatinib as Mesylate…….400 mg	
	Diary No. Date of R & I & fee	Dy. No 12767 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Tyrosine Kinase Inhibitor	
	Type of Form	Form-5	
	Finished product Specification	Innovator specification	
	Pack size & Demanded Price	30',90's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	MHRA. Glivec 100mg & 400mf f/c tablet by M/s Novartis.	
	Me-too status	087793, IM-Tab Tablet 400mg ,M/s Werrick Pharmaceuticals, Islamabad.	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations.	

		Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved	
686.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	TRAMAX-SR Tablet 100 mg
	Composition	Each Film Coated Tablet Contains: zafirlukast……10 mg
	Diary No. Date of R & I & fee	Dy. No 12730 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Selective and competitive receptor antagonist of Leukotriene D4 and E4.
	Type of Form	Form-5
	Finished product Specification	Innovator specification
	Pack size & Demanded Price	10's,14's,20's,28's,30' As per SRO
	Approval status of product in Reference Regulatory Authorities	ACCOLATE of (USFDA approved)
	Me-too status	Zilesta 10mg Tablet of M/s Genix Pharma
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved	
687.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	CERTIVIN Capsule 150mg
	Composition	Each Capsule Contains: Ceritinib……150 mg
	Diary No. Date of R & I & fee	Dy. No 12760 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Selective Inhibitor of anaplastic lymphoma kinase
	Type of Form	Form-5
	Finished product Specification	innovator specification
	Pack size & Demanded Price	50's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Cap ZYKADIA 150 mg USFDA discontinued.
	Me-too status	Zykadia 150Mg Hard Gelatin Capsules, 088399, Novartis Pharma (Pak) Ltd.,Karachi
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm

		M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator	• Provided RRA reference of USFDA of Cap ZYKADIA is discontinued. Provide valid RRA registration status.	• Firm has submitted reply and RRA reference of TGA approved product, Capsule Zykadia 150 mg ,Sponsor:Novartis Pharmaceuticals Australia Pty Limited, Australia.
	Decision: Approved		
688.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	SOLAP Injection 200 mg/20 ml	
	Composition	Each 20 ml Vial Contains: Lacosamide ……200 mg	
	Diary No. Date of R & I & fee	Dy. No 12748 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antiepileptic	
	Type of Form	Form-5	
	Finished product Specification	Innovator specification	
	Pack size & Demanded Price	1's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA	
	Me-too status	Lacolep 10mg/ml Injection (20ml) of Hilton Pharma	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator	Innovator Specs	
	Decision: Approved with innovator specifications.		
689.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.	
	Brand Name + Dosage Form + Strength	GRANISOL Injection 3mg/3 ml	
	Composition	Each 3ml ampoule contains: Granisetron Hydrochloride eq, to Granisetron…….3 mg	
	Diary No. Date of R & I & fee	Dy. No 12763 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antiemetic	
	Type of Form	Form-5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	1's,5's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Granisetron 1 mg/ml concentrate for solution for injection or infusion (3ML AMPOULE) by M/s Hameln Pharma gmbh, MHRA Approved.	
	Me-too status	Granicip injection (3mg/3ml) by M/s AJ Mirza pharma (pvt) ltd., Reg. No. 52261	
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment,	

		personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved.	
690.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	IROTICAN Injection 100mg/5 ml
	Composition	Each 5ml vial contains: Irinotecan Hydrochloride as Trihydrate ……100 mg
	Diary No. Date of R & I & fee	Dy. No 12750 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Topoisomerase I inhibitor
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Campto Injection 100mg/5ml of M/s Pfizer (Reg # 021128) Irinotecan Injection 100mg/5ml of M/s Novartis (Reg# 066187)
	Me-too status	Pipetecan 100mg/5ml Injection, 092306, Rotex Pharma (Pvt) Ltd.,Islamabad
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved.	
691.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	VINOBIN Injection 50mg/5 ml
	Composition	Each 5ml vial contains: Vinorelbine as tartrate……..……50 mg
	Diary No. Date of R & I & fee	Dy. No 12752 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Semi synthetic Vinca-Alkaloid/ antitumor activity
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	1's,As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved, Vinorelbine (as Tartrate) 50mgl5ml sterile concentrate.
	Me-too status	Vinorelbine Karma 10mg/ml (50mg/5ml)concentrate for Solution for Injection, 101954, Lab Diagnostic System (Pvt) Ltd,Rawalpindi.
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment,

		personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved.	
692.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	SOQUIN Cream 2% w/w
	Composition	Each gram of cream contains: Hydroquinone……20 mg
	Diary No. Date of R & I & fee	Dy. No 12741 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Depigmentation agent
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	5 gm,10gm,15gm, 20 gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Symba Skin Toner Cream by M Sarner (1969) Limited. MHRA approved
	Me-too status	Dermoquin 2% Cream by Wilson Pharma (Reg No. 007581)
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".
	Remarks of the Evaluator	
	Decision: Approved.	
693.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No.549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	TAZOMIL GEL 0.05% w/w
	Composition	Each gram of gel contains: Tazarotene……0.5 mg
	Diary No. Date of R & I & fee	Dy. No 12743 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Anti-psoriasis
	Type of Form	Form-5
	Finished product Specification	Innovator specification
	Pack size & Demanded Price	5 gm,10gm,15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	ZORAC 0.05%, gel by M/s Allergan Pharmaceuticals Ireland (MHRA Approved)
	Me-too status	Trazene 0.05% Gel by M/s PharmEvo (Pvt.) Ltd. (Reg#057748)
	GMP status	**The Last GMP inspection was conducted on 08-07-2019 & 25-07-2019 with following recommendations:** "The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations.

		Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance".	
	Remarks of the Evaluator		
	Decision: Approved		
694.	Name and address of manufacturer/ Applicant	Sharex Laboratories (Pvt)Ltd., K.L.P Road, Sadiqabad.	
	Brand Name + Dosage Form + Strength	Sterile Water of Injection (IM/IV)	
	Composition	Each Ampoule Contains: Water for Injection……2 ml/3ml/5ml/10ml	
	Diary No. Date of R & I & fee	Dy. No 3333 (R&I) dated 21-12-2016; Rs.20,000/- dated 20-12-2016, **DUPLICATE DOSSIER** Dy.No.8743(R&I) dated 05-04-2022.	
	Pharmacological Group	Solvent	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer Specifications.	
	Pack size & Demanded Price	2 ml.3.50/,3ml.4.50/,5ml.5.10/,10ml.10.70/.	
	Approval status of product in Reference Regulatory Authorities	Sterile water for injection, USFDA approved.	
	Me-too status	Sterile water for injection: 5ml, Aquason Injection, 083140, Hudson Pharma (Pvt) Ltd., D-93 Port Qasim Authority Karachi, Karachi.	
	GMP status	As per available record, last GMP inspection was conducted on 29-03-2017 which concluded as, "the operations of manufacturing and QC were found satisfactory to GMP compliance on the day of inspection."	
	Remarks of the Evaluator	• GMP certificate/inspection conducted with last 3 years is required. • Firm has applied 4 fill volumes of ampoules of 2ml,3ml,5ml & 10 ml in same application. Only one application can be applied per application. • The official monograph is present in B.P and USP. • The duplicate application (form 5) is forwarded by Reg II vide letter No.F.1-11/2019-Reg-II dated 29-06-2022 with Dairy No. 1513 (R-V) & dated 22-12-2016 of Registration Section II, where they have mentioned that above application is verified from Dairy record of R-II section for further processing. (photocopy of section dairy page of the register is also enclosed.)	• Firm has submitted reply and choose 5 ml ampoule of sterile water for injection along with revised finished product specification as USP specs. Firm has also submitted DML renewal inspection conducted on 13-04-2021 &14-04-2021, in which panel had recommended DML renewal. • Firm has submitted fee preregistration variation fee challan No. 38696578627 of 7500/=
	Decision: Approved with USP specification (5 ml ampoule.)		

695.	Name and address of manufacturer/ Applicant	Sharex Laboratories (Pvt)Ltd., K.L.P Road, Sadiqabad.	
	Brand Name + Dosage Form + Strength	Lignocaine Injection 1 %	
	Composition	Each ml of Ampoule Contains: Lignocaine Hydrochloride…….10 mg	
	Diary No. Date of R & I & fee	Dy. No 3334 (R&I) dated 21-12-2016; Rs.20,000/- dated 20-12-2016, **DUPLICATE DOSSIER** Dy.No.8744(R&I) dated 05-04-2022.	
	Pharmacological Group	Solvent	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer Specifications.	
	Pack size & Demanded Price	2 ml. Rs 5/, 5 ml. Rs 12.50/=	
	Approval status of product in Reference Regulatory Authorities	MHRA approved, Injection Lidocaine Hcl 1 % w/v.	
	Me-too status	Lignocaine 1% Injection, 074295, Wilshire Laboratories (Pvt) Ltd., Lahore.	
	GMP status	As per available record, last GMP inspection was conducted on 29-03-2017 which concluded as, "the operations of manufacturing and QC were found satisfactory to GMP compliance on the day of inspection."	
	Remarks of the Evaluator	• GMP certificate/inspection conducted with last 3 years is required. • Firm has applied 2 fill volumes of ampoules of 2ml & ,5ml in same application.one fill volume can be applied per application. • The official monograph is present in B.P s • The duplicate application (form 5) is forwarded by Reg II vide letter No.F.1-11/2019-Reg-II dated 29-06-2022 with Dairy No. 1514 (R-V) & dated 22-12-2016 of Registration Section II, where they have mentioned that above application is verified from Dairy record of R-II section for further processing. (photocopy of section dairy page of the register is also enclosed.)	• Firm has submitted reply and choose 2 ml ampoule of Lignocaine injection 1% along with revised finished product specification as USP specs. Firm has also submitted DML renewal inspection conducted on 13-04-2021 &14-04-2021, in which panel had recommended DML renewal. • Firm has submitted fee preregistration variation fee challan No. 33730632 of 7500/=
	Decision: Approved with USP specification (2 ml ampoule)		
696.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	TEGLIP Tablet 20 mg	
	Composition	Each Film Coated Tablet Contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin……20 mg	
	Diary No. Date of R & I & fee	Dy. No 11977 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Antidiabetic	
	Type of Form	Form – 5D	

	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	7's,14's,28's,10's,20's &30's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Tablet Tenelia, Mitsubishi Tanabe Pharma, PMDA Japan.	
	Me-too status	Not provided.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	• Form submitted reply and submitted me-too reference as tablet Tenliptin,Reg # 105239,Indus Pharma , the same is not verifiable from available record. • Firm has submitted scan copy of Form-5 annexure on prescribed format.
	Decision: Deferred for following • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.**		
697.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	LORCAS Tablet 10 mg	
	Composition	Each Film Coated Tablet Contains: Lorcaserin Hcl Hemihydrate eq.to Lorcaserin……10 mg	
	Diary No. Date of R & I & fee	Dy. No 11967 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	AntiObesity	
	Type of Form	Form – 5D	
	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	10's,20's,30's,50, s,100's As per SRO.	
	Approval status of product in Reference Regulatory Authorities	USFDA Tentative approved.	
	Me-too status	Not provided.	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	

	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.
	Decision: Deferred for following • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.** • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976**	
698.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	ASINAP Tablet 10 mg
	Composition	Each Sublingual Tablet Contains: Asenapine Maleate eq.to Asenapine……10 mg
	Diary No. Date of R & I & fee	Dy. No 11974 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Antipsychotic
	Type of Form	Form – 5D
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	20's,60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA approved, Tablet Sycrest 10 mg,
	Me-too status	Not provided.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.
	Decision: Deferred for following • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.** • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976**	
699.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	PRULOP Tablet 1mg
	Composition	Each Film Coated Tablet Contains: Prucalopride succinate eq to Prucalopride……..1mg
	Diary No. Date of R & I & fee	Dy. No 11966 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	5-HT4 receptor agonist, Gut motility enhancer.
	Type of Form	Form – 5D

	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	10's,20's,30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA approved, Tablet Resolor 1 mg
	Me-too status	Not provided.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.
	Decision: Deferred for following • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.** • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976**	
700.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	BRIXAB Capsule 40 mg
	Composition	Each Capsule Contains: Betrixaban Maleate eq.to Betrixaban……...40 mg
	Diary No. Date of R & I & fee	Dy. No 11965 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Factor Xa Inhibitor
	Type of Form	Form – 5D
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	10's,20's,30's,100's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA marketing status discontinued. Cap BEVYXXA 40 mg.
	Me-too status	Not provided.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.

	Decision: Deferred for following • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.** • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
701.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	PENTOSAL Capsule 100 mg
	Composition	Each Capsule Contains: Pentosan Polysulfate Sodium……...100 mg
	Diary No. Date of R & I & fee	Dy. No 11955 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Vasoprotective
	Type of Form	Form – 5D
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cap ELMIRON 100 mg, USFDA approved.
	Me-too status	Not provided.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.
	Decision: Deferred for following • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.** • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976**	
702.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	LEVUNIC Gel
	Composition	Each One Gram Gel Contains: 5-Aminolaevulinic Acid (as Hydrochloride) ……...78 mg
	Diary No. Date of R & I & fee	Dy. No 11960 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Antineoplastic agent, L01XD04
	Type of Form	Form – 5D
	Finished product Specification	Not provided
	Pack size & Demanded Price	2 gm, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Not traceable
	Me-too status	Not provided.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people*

		met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Anticancer gel section approval from CLB. • Finished product specification • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.
	Decision: Deferred for following • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.** • **Anticancer gel section approval from CLB.** • **Finished product specification** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.**	
703.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	NOCHOL Sachet 4 gm (orange flavor)
	Composition	Each Sachet Contain: Cholestyramine……...4 gm
	Diary No. Date of R & I & fee	Dy. No11939 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Bile acid sequestrants, ATC code: C10AC01
	Type of Form	Form – 5D
	Finished product Specification	USP
	Pack size & Demanded Price	30's,50's'60's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Cholestyramine 4GM Powder for oral suspension of Bristol Myers (Discontinued in USFDA) **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons
	Me-too status	Not provided.
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.

	Decision: Deferred for following **•Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** **•Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.** **•Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.**		
704.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	NETCIN Ophthalmic Suspension	
	Composition	Each ml of Ophthalmic Suspension Contains: Natamycin…….……50 mg (5 %)	
	Diary No. Date of R & I & fee	Dy. No11982 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Antibiotics	
	Type of Form	Form – 5D	
	Finished product Specification	USP	
	Pack size & Demanded Price	15 ml, As per DPC	
	Approval status of product in Reference Regulatory Authorities	NATACYN 5 % ophthalmic suspension, USFDA approved	
	Me-too status	Zolvin Eye Drops., 040117, Zinta Pharmaceuticals Industry, Peshawar	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	Firm has submitted scan copy of Form-5 annexure on prescribed format.
	Decision: Approved The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
705.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.	
	Brand Name + Dosage Form + Strength	FLUTIM NEBULES, Inhalation Suspension for Nebulization,0.5 mg/2ml	
	Composition	Each 2 ml plastic ampoule contains: Fluticasone Propionate…….0.5 mg	
	Diary No. Date of R & I & fee	Dy. No. 11959 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Glucocorticoids	
	Type of Form	Form – 5D	
	Finished product Specification	Innovators specification	
	Pack size & Demanded Price	10's.20's, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Not traceable	
	Me-too status	Not provided	
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*	
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.	

		• Section approval letter for plastic Ampoule section (Steroid) from CLB. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.
	Decision: Deferred for following shortcomings: • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.** • **Section approval letter for plastic Ampoule section (Steroid) from CLB.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.**	
706.	Name and address of manufacturer/ Applicant	Genix Pharma (Pvt) Ltd.44,45-B, Korangi Chowk Road, Karachi.
	Brand Name + Dosage Form + Strength	FLUTIM NEBULES, Inhalation Suspension for Nebulization,2mg/2ml
	Composition	Each 2 ml plastic ampoule contains: Fluticasone Propionate…….2 mg
	Diary No. Date of R & I & fee	Dy. No. 11958 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Glucocorticoids
	Type of Form	Form – 5D
	Finished product Specification	Innovators specification
	Pack size & Demanded Price	10's.20's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Not traceable
	Me-too status	Not provided
	GMP status	GMP inspection was conducted on 12-02-2020 and concluded as, "*Based on the area inspected, the people met and the document reviewed and considering the findings of the inspection including the observation listed above M/s Genix Pharma Private Limited Located at Plot No.44-45-B Korangi, Creek Road Karachi, Pakistan was considered to be operating at a good level of compliance with cGMP guideline as of today."*
	Remarks of the Evaluator	• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976. • Section approval letter for plastic Ampoule section (Steroid) from CLB. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.
	Decision: Deferred for following shortcomings: • **Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976.** • **Section approval letter for plastic Ampoule section (Steroid) from CLB.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	

	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. **• Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.**		
707.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.	
	Brand Name + Dosage Form + Strength	DEXLANSO Capsule 30 mg	
	Composition	Each Capsule Contains: Dexlansoprazole (22.5 % EC pellets) ……30 mg	
	Diary No. Date of R & I & fee	Dy. No.11767 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-Ulcerant	
	Type of Form	Form-5	
	Finished product Specification	Inhouse	
	Pack size & Demanded Price	30's, As per DPC.	
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA Dexilant Capsule	
	Me-too status	Razodex of Getz Pharma	
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.	
	Remarks of the Evaluator	• Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Firm has not provided source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. • Form-5 label claim does not does not mentioned pellets, however master formulation does mentioned pellets, provide revised form 5 label claim	Firm has submitted reply with fee challan No. 105776623168 along with revised Form-5 mentioning, Each delayed Release Capsule contains; Dexlansoprazole Enteric Coated Pellets…….30 mg. Firm also submitted COA and stability data of Pellets of Vision Pharmaceuticals (Pvt) Ltd Islamabad. Firm also submitted undertaking that they will conduct stability study for real time and accelerated.
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board is required.		
708.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.	
	Brand Name + Dosage Form + Strength	DEXLANSO Capsule 60 mg	
	Composition	Each Capsule Contains: Dexlansoprazole (22.5 % EC pellets) ……60 mg	
	Diary No. Date of R & I & fee	Dy. No.11768 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-Ulcerant	
	Type of Form	Form-5	
	Finished product Specification	Inhouse	
	Pack size & Demanded Price	30's, As per DPC.	
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA Dexilant Capsule	
	Me-too status	Razodex of Getz Pharma	
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.	

	Remarks of the Evaluator	• Stability study data as per guidelines provided in 293rd meeting of Registration Board is required. • Firm has not provided source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	Firm has submitted reply with revised Form-5 mentioning, Each delayed Release Capsule contains; Dexlansoprazole Enteric coated Pellets…….60 mg. Firm also submitted COA and stability data of Pellets of Vision Pharmaceuticals (Pvt) Ltd Islamabad. Firm also submitted undertaking that they will conduct stability study for real time and accelerated.
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board is required.		
709.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.	
	Brand Name + Dosage Form + Strength	E-Glif Tablet 10 mg	
	Composition	Each Film Coated Tablet Contains: Empagliflozin……10mg	
	Diary No. Date of R & I & fee	Dy. No.11773 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-Diabetic	
	Type of Form	Form-5	
	Finished product Specification	Inhouse	
	Pack size & Demanded Price	30's, As per DPC.	
	Approval status of product in Reference Regulatory Authorities	Jardiance Tablets 10mg of M/s BOEHRINGER INGELHEIM (USFDA Approved).	
	Me-too status	Diampa Tablets 10mg by M/s Getz Pharma Reg. No. 093073	
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.	
	Remarks of the Evaluator	• Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	• Firm also submitted undertaking that they will conduct stability study for real time and accelerated
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board is required.		
710.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.	
	Brand Name + Dosage Form + Strength	E-Glif Tablet 20 mg	
	Composition	Each Film Coated Tablet Contains: Empagliflozin……20mg	
	Diary No. Date of R & I & fee	Dy. No.11774 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-Diabetic	
	Type of Form	Form-5	
	Finished product Specification	Inhouse	
	Pack size & Demanded Price	30's, As per DPC.	
	Approval status of product in Reference Regulatory Authorities	Jardiance Tablets 25mg, USFDA Approved.	
	Me-too status	Diampa Tablets 25mg by M/s Getz Pharma Reg. No. 093074	

	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.	
	Remarks of the Evaluator	• Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	• Firm also submitted undertaking that they will conduct stability study for real time and accelerated
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board is required.		
711.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.	
	Brand Name + Dosage Form + Strength	MERIGON Tablet 25 mg	
	Composition	Each prolonged release Tablet Contains: Mirabegron……25mg	
	Diary No. Date of R & I & fee	Dy. No.11765 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Urinary Antispasmodic	
	Type of Form	Form-5	
	Finished product Specification	Inhouse	
	Pack size & Demanded Price	10's, As per DPC.	
	Approval status of product in Reference Regulatory Authorities	BETMIGA mirabegron 25 mg film-coated prolonged release tablet, TGA approved.	
	Me-too status	Mibega Tablets 25mg, Getz Pharma, Reg. No. 089375	
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.	
	Remarks of the Evaluator	• Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.	• Firm also submitted undertaking that they will conduct stability study for real time and accelerated
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board is required.		
712.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.	
	Brand Name + Dosage Form + Strength	TAMSIFLO Capsule	
	Composition	Each Capsule Contains: Tamsulosin Hcl (Modified release pellets) ……..0.4mg	
	Diary No. Date of R & I & fee	Dy. No.11702 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Alpha 1 A Antagonist	
	Type of Form	Form-5	
	Finished product Specification	USP	
	Pack size & Demanded Price	10's, As per DPC.	
	Approval status of product in Reference Regulatory Authorities	FLOMAX capsule by Boehringer Ingelheim (USFDA Approved)	
	Me-too status	Tamflo 0.4mg Capsule by Genome Pharmaceutical	
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.	
	Remarks of the Evaluator	Firm has not provided source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	Firm also submitted COA and stability data of Pellets of Vision Pharmaceuticals (Pvt) Ltd Islamabad, however the submitted GMP certificate of Vision Pharmaceuticals (Pvt) Ltd is expired.
	Decision: Approved , Firm shall submit valid copy of GMP certificate of source of their pellets.		

713.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	RELCOMB Ear Drops
	Composition	Each ML contains: Gramicidin……0.225 mg Neomycin Sulphate……2.25 mg Nystatin…….90000 IU Triamcinolone acetonide……0.9 mg
	Diary No. Date of R & I & fee	Dy. No.11751 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antifungal/Corticosteroid
	Type of Form	Form-5
	Finished product Specification	Manufacturer Spec.
	Pack size & Demanded Price	10 ml, As per DPC.
	Approval status of product in Reference Regulatory Authorities	TGA approved ,Kenacomb Otic ear drops.
	Me-too status	Xecomb Ear Drops, 048526, Triamcinolone Acetonide……1mgNeomycin Base (as Sulphate)……...2.5mgGramicidin……0.25mg Nystatin……..100,000 units , Elko Org , Karachi,
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
	Remarks of the Evaluator	Provided Me to reference does not comply with same strength of active ingredients.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm	
714.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	FUSIREM-H Cream
	Composition	Each Gram Contains: Fusidic Acid…….20 mg Hydrocortisone acetate…….10 mg
	Diary No. Date of R & I & fee	Dy. No.11743 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antibiotic/Corticosteroid
	Type of Form	Form-5
	Finished product Specification	Inhouse Spec.
	Pack size & Demanded Price	5 gm, As per DPC.
	Approval status of product in Reference Regulatory Authorities	Fucidin – H Cream (MHRA approved).
	Me-too status	Fucort – H Cream by Saffron (Reg. # 089436).
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
	Remarks of the Evaluator	
	Decision: Approved with innovator specifications.	
715.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	RETAVAL Ointment 0.1 % w/w
	Composition	Each Gram of Ointment Contains: Betamethasone as valerate ……1 mg
	Diary No. Date of R & I & fee	Dy. No.11755 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Topical Corticosteroid
	Type of Form	Form-5
	Finished product Specification	USP Spec.
	Pack size & Demanded Price	15 gm, As per DPC.

	Approval status of product in Reference Regulatory Authorities	MHRA Approved.
	Me-too status	Betnovate ointment by GSK
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
	Remarks of the Evaluator	
	Decision: Approved.	
716.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	AVIRONE Ointment 0.1 %
	Composition	Each Gram of Ointment Contains: Methylprednisolone aceponate…….1 mg
	Diary No. Date of R & I & fee	Dy. No.11770 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Topical Corticosteroid
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	5 gm & 10 gm, As per DPC.
	Approval status of product in Reference Regulatory Authorities	ADVANTAN Methylprednisolone Aceponate 1mg/g ointment tube. TGA approved.
	Me-too status	Depomax Ointment 1mg/g of M/s. Shaigan Pharmaceuticals, Rawalpindi Reg. No. 083598
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
	Remarks of the Evaluator	
	Decision: Approved with innovator specification. The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012-B&A/DRAP dated 13-07-2021	
717.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	REMPIR Ointment 2 %
	Composition	Each Gram of Ointment Contains: Mupirocin……20 mg
	Diary No. Date of R & I & fee	Dy. No.11761 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	15 gm, As per DPC.
	Approval status of product in Reference Regulatory Authorities	Bactroban 2% Ointment MHRA approved
	Me-too status	Muricin 2% Ointment by M/s Crystolite Pharma (Reg#077628)
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
	Remarks of the Evaluator	
	Decision:Approved.	
718.	Name and address of manufacturer/ Applicant	Remington Pharmaceutical Industries (Pvt.) Ltd. ,18 Km Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	TACILUS Ointment 0.03 %
	Composition	Each Gram of Ointment Contains: Tacrolimus Monohydrate eq.to Tacrolimus…….0.3 mg
	Diary No. Date of R & I & fee	Dy. No.11758 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5

	Finished product Specification	Inhouse
	Pack size & Demanded Price	10 gm,30 gm, As per DPC.
	Approval status of product in Reference Regulatory Authorities	Protopic (0.03%, 0.1%) ointment USFDA approved
	Me-too status	Graftil 0.1% Ointment by M/s Biolabs (Pvt) Ltd (Reg#096755)
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
	Remarks of the Evaluator	
	Decision: Approved with innovator specification. The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012-B&A/DRAP dated 13-07-2021	
719.	Name and address of manufacturer/ Applicant	Friends Pharma (Pvt) Ltd.31-Km Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	FEMIZOLE Tablet 2.5 mg
	Composition	Each Enteric Coated Tablet Contains: Letrozole…….2.5 mg
	Diary No. Date of R & I & fee	Dy. No.448 dated 31-03-2015; Rs.20,000/- dated 31-03-2015. **Duplicate Dossier** Dy. No1007 dated 11-01-2022.
	Pharmacological Group	Non-steroidal aromatase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per DPC.
	Approval status of product in Reference Regulatory Authorities	FEMARA (Novartis) US FDA approved
	Me-too status	Oreta 2.5mg tablet of M/s Aries pharma, Peshawar. Registration No. 085909
	GMP status	DML renewal inspection was conducted on 08-03-2019 and recommends the renewal of DML.
	Remarks of the Evaluator	• Applied product is film enteric coated product, however no coating material is mentioned in master formulation. moreover, in manufacturing method firm mentioned Methylene chloride, Revised Master formulation and correct manufacturing method without methylene chloride is required. • GMP inspection /certificate within last 3 years is required.
	Decision: Approved with innovator's specification Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Firm shall submit revised master formulation mentioning coating material and Valid copy of GMP certificate /inspection report before issuance of Registration letter. The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
720.	Name and address of manufacturer/ Applicant	Friends Pharma (Pvt) Ltd.31-Km Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	FROXICAM Tablet 8 mg
	Composition	Each Enteric Coated Tablet Contains: Lornoxicam…….8 mg
	Diary No. Date of R & I & fee	Dy. No.445 dated 31-03-2015; Rs.20,000/- dated 31-03-2015. **Duplicate Dossier** Dy. No.1005 dated 11-01-2022.
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per DPC.
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too status	Recam Tablet 8 mg by M/s Regal Pharmaceuticals

		(Reg.#081952)
	GMP status	DML renewal inspection was conducted on 08-03-2019 and recommends the renewal of DML.
	Remarks of the Evaluator	• Applied product is enteric coated product, however reference product is film coated product more no coating material is mentioned in master formulation. Revised label claim and Master formulation is required. • GMP inspection /certificate within last 3 years is required.
	Decision: Approved with innovators specification as Film coated tablet. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Firm shall submit revised master formulation mentioning filmcoating material and valid copy of GMP certificate /inspection report before issuance of Registration letter. The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
721.	Name and address of manufacturer/ Applicant	Friends Pharma (Pvt) Ltd.31-Km Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	FROXIN-CR Tablet
	Composition	Each Controlled Release Tablet Contains: Paroxetine (as Hcl) …….25 mg
	Diary No. Date of R & I & fee	Dy. No.454 dated 31-03-2015; Rs.20,000/- dated 31-03-2015. **Duplicate Dossier** Dy. No.1006 dated 11-01-2022.
	Pharmacological Group	Antidepressant/SSRI
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per DPC.
	Approval status of product in Reference Regulatory Authorities	Paxil CR tablets (USFDA),
	Me-too status	Seroxat CR by GSK
	GMP status	DML renewal inspection was conducted on 08-03-2019 and recommends the renewal of DML.
	Remarks of the Evaluator	• GMP inspection /certificate within last 3 years is required. • Reference product is enteric coated, Controlled release; however, the enteric coating is not mentioning in master formulation and manufacturing method.
	Decision: Approved. Rgsitration letter wil be issued upon submission of revised composition and label claim as per innovator product along with fee of Rs. 30,000/- for change/correction in composition as per notification no. as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
722.	Name and address of manufacturer/ Applicant	Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore
	Brand Name + Dosage Form + Strength	MALIQUIN Sachet
	Composition	Each Sachet Contains: Dihydroartemisinic…….15 mg Piperaquine Phosphate……120 mg
	Diary No. Date of R & I & fee	Dy. No.6143 dated 14-06-2017; Rs.20,000/- dated 14-06-2017. **Duplicate Dossier** Dy. No10010 dated 20-04-2022.
	Pharmacological Group	Anti-Malarial
	Type of Form	Form-5
	Finished product Specification	Innovator specification
	Pack size & Demanded Price	As per DPC.
	Approval status of product in Reference Regulatory Authorities	Not traceable
	Me-too status	TIMEQUIN SACHET 15/120 by M/s SAMI PHARMACEUTICALS (PVT) LTD, Reg No. 70787

	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
723.	Name and address of manufacturer/ Applicant	Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore
	Brand Name + Dosage Form + Strength	ERDOSTENE Sachet
	Composition	Each Sachet Contains: Erdosteine……225 mg
	Diary No. Date of R & I & fee	Dy. No.6144 dated 14-06-2017; Rs.20,000/- dated 14-06-2017. **Duplicate Dossier** Dy. No10015 dated 20-04-2022.
	Pharmacological Group	Expectorant
	Type of Form	Form-5
	Finished product Specification	Biomark specification
	Pack size & Demanded Price	As per DPC.
	Approval status of product in Reference Regulatory Authorities	Not traceable
	Me-too status	Erdozet Sachet 225 mg by M/s Wenovo Pharmaceuticals (Reg# 078072)
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
724.	Name and address of manufacturer/ Applicant	Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore
	Brand Name + Dosage Form + Strength	BIDOPA Tablet
	Composition	Each Film Coated Tablet Contains: Levodopa……250 mg Carbidopa……25 mg
	Diary No. Date of R & I & fee	Dy. No.10926 dated 05-03-2019; Rs.20,000/- dated 14-06-2017. **Duplicate Dossier** Dy. No 33915 dated 28-12-2021.
	Pharmacological Group	Anti-Parkinsonism
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	30's,100's,As per DPC.
	Approval status of product in Reference Regulatory Authorities	Co-Careldopa 25 mg/250 mg tablets. MHRA approved
	Me-too status	Validopa Tablets. Reg. No. 31109
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board	
725.	Name and address of manufacturer/ Applicant	Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore
	Brand Name + Dosage Form + Strength	OTILIUM Tablet
	Composition	Each Film Coated Tablet Contains: Otilonium Bromide ……40 mg
	Diary No. Date of R & I & fee	Dy. No.6110 dated 14-06-2017; Rs.20,000/- dated 13-06-2017. **Duplicate Dossier** Dy. No 10013 dated 20-04-2022.
	Pharmacological Group	anticholinergic, quaternary ammonium compounds

	Type of Form	Form-5
	Finished product Specification	Innovator specification
	Pack size & Demanded Price	20's, As per DPC.
	Approval status of product in Reference Regulatory Authorities	Spasmomen of Italy, Otilonio Stada 40 mg by Laboratorio Stada, Sl (Spain Approved)
	Me-too status	Spasmomen tablet 40mg of Pharmatech.
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board	
726.	Name and address of manufacturer/ Applicant	Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore
	Brand Name + Dosage Form + Strength	LACOS Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide……200 mg
	Diary No. Date of R & I & fee	Dy. No.21240 dated 16-11-2017; Rs.20,000/- dated 13-11-2017. **Duplicate Dossier** Dy. No 10012 dated 20-04-2022.
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specification	Innovator specification
	Pack size & Demanded Price	20's, As per DPC.
	Approval status of product in Reference Regulatory Authorities	Vimpat 200mg tablet of M/s UCB Pharma Limited, UK (MHRA Approved)
	Me-too status	Otomin Tablet by Genome Pharma (Reg # 059407)
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board	
727.	Name and address of manufacturer/ Applicant	Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore
	Brand Name + Dosage Form + Strength	SEDAP Tablet
	Composition	Each Enteric Coated Tablet Contains: Serratiopeptidase……10 mg
	Diary No. Date of R & I & fee	Dy. No.10928 dated 05-03-2019; Rs.20,000/- dated 28-02-2019. **Duplicate Dossier** Dy. No 33915 dated 28-12-2021
	Pharmacological Group	Anti-Inflammatory Enzyme
	Type of Form	Form-5
	Finished product Specification	Innovator specification
	Pack size & Demanded Price	10's,20's,100's, As per DPC.
	Approval status of product in Reference Regulatory Authorities	Not traceable
	Me-too status	Danzen DS Tab, Helix pharma, Reg. No. 028173.
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
728.	Name and address of manufacturer/ Applicant	Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore
	Brand Name + Dosage Form + Strength	MENTINE Oral syrup
	Composition	Each 5 ml Contains:

		Memantine Hydrochloride……10mg	
	Diary No. Date of R & I & fee	Dy. No.6181 dated 14-06-2017; Rs.20,000/- dated 13-06-2017. **Duplicate Dossier** Dy. No 10014 dated 20-04-2022	
	Pharmacological Group	Glutamate NDMA receptor Antagonist	
	Type of Form	Form-5	
	Finished product Specification	Innovator specification	
	Pack size & Demanded Price	1*120ml, As per DPC.	
	Approval status of product in Reference Regulatory Authorities	Not provided	
	Me-too status	Mantin Syrup by M/s Pharmasol (Pvt) Ltd (Reg# 089890)	
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020	
	Remarks of the Evaluator	evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.		
729.	Name and address of manufacturer/ Applicant	Applicant /Contract giver: Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore. Manufacturer / Contract acceptor: Bio Lab, (Pvt) Ltd, plot No.145, Industrial Triangle,Kahuta Road,Islamabad.	
	Brand Name + Dosage Form + Strength	UCON Infusion 100 ml (200mg/vial)	
	Composition	Each ml Infusion Contain: Fluconazole …….2mg	
	Diary No. Date of R & I & fee	Dy. No.19500 dated 30-10-2017; Rs.50,000/- dated 30-10-2017. **Duplicate Dossier** Dy. No 10011 dated 20-04-2022	
	Pharmacological Group	Antifungal	
	Type of Form	Form-5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	1*100ml, Amber type II glass vial. As per DPC.	
	Approval status of product in Reference Regulatory Authorities	Fluconazole 200 mg/100 ml (2mg/ml) Fresenius Kabi USA (USFDA Approved-076145) & Diflucan (Fluconazole) 200 mg/100 ml injection vial by Pfizer Australia Pty Ltd (TGA Approved). It is also approved by EMA (European Medicine Agency), UK MHRA & PMDA (Japan).	
	Me-too status	Fluzone Infusion of M/s Pharmedic (Pvt.) Ltd, (Reg. # 025995)	
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020	
	Remarks of the Evaluator	• Original Contract manufacturing agreement mentioning quality policy and mandate to procure API raw materials, excipients ad packaging material. • Form-5 covering letter dully signed by applicant. • GMP inspection /Certificate of contract manufacturer within last 3 years.	• Firm has submitted reply vide diary No.2016 PEC DRAP dated 30/08/2022 along with form-5 covering letter dully singed by applicant, i-e M/s Biomark Pharmaceutical, Lahore, • Firm has also submitted copy of GMP certificate of contract acceptor ,M/s Bio Labs (Pvt) Ltd, Islamabad, mentioning Liquid Infusion section (100 ml)

		• Section approval letter from CLB.	
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board		
730.	Name and address of manufacturer/ Applicant	Bio-Mark Pharmaceuticals, plot No.527, Sunder industrial Estate Lahore	
	Brand Name + Dosage Form + Strength	LIVPAR Oral Syrup	
	Composition	Each 5 ml Contains: Betaine Glucuronate……3.750 gm Diethanolamine Glucuronate……1.0 gm Nicotinamine……0.200 gm	
	Diary No. Date of R & I & fee	Dy. No.10872 dated 05-03-2019; Rs.20,000/- dated 01-03-2019. **Duplicate Dossier** Dy. No 33916 dated 28-12-2021	
	Pharmacological Group	Amino acid/vitamins	
	Type of Form	Form-5	
	Finished product Specification	Innovator specification	
	Pack size & Demanded Price	1*120ml, As per DPC.	
	Approval status of product in Reference Regulatory Authorities	Not provided.,	
	Me-too status	002188, Jetepar Syrup,	
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020	
	Remarks of the Evaluator		
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.		
731.	Name and address of manufacturer/ Applicant	Shrooq Pharmaceutical (Pvt) Ltd,21-KM, Feroze Pur Road, Lahore	
	Brand Name + Dosage Form + Strength	PANCRO Injection I.V (4 mg/2ml)	
	Composition	Each ml contains: Pancuronium Bromide…….2 mg	
	Diary No. Date of R & I & fee	Dy. No.684 dated 11-04-2014; Rs.20,000/- dated 11-04-2014. **Duplicate Dossier** Dy. No13049 dated 28-05-2022	
	Pharmacological Group	Muscle relaxant	
	Type of Form	Form-5	
	Finished product Specification	BP specification.	
	Pack size & Demanded Price	Ampoule of 2 ml, As per DPC	
	Approval status of product in Reference Regulatory Authorities	Pancuronium Injection 4mg/2ml of Mercury Pharma, Ireland.(MHRA approved)	
	Me-too status	Pancron injection of Brookes Pharma (Reg#020299)	
	GMP status	DML renewal inspection conducted on 26-10-2021 & 29-10-2021 and panel recommended renewal of DML for following sections, Tablet (general) , Tablet (quinolone), Oral Liquid , Capsule (general) , Sachet , Capsule (ceph) ,Dry Powder Suspension (ceph),Topical (cream/ointment, lotion and gel) , Dry Powder Injection(ceph) , Injection ampoule (general) , Vial Infusion , Eye/Ear/Nose Drops (New),Capsule (steroid) (new, revised).	
	Remarks of the Evaluator		
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board		
732.	Name and address of manufacturer/ Applicant	Shrooq Pharmaceutical (Pvt) Ltd,21-KM, Feroze Pur Road, Lahore	
	Brand Name + Dosage Form + Strength	FANTAL Injection (I/M, I/V)	
	Composition	Each 5ml contains: Fentanyl Citrate……0.5 mg	
	Diary No. Date of R & I & fee	Dy. No.687dated 11-04-2014; Rs. 20,000/- dated 11-04-2014. **Duplicate Dossier** Dy. No 13050 dated 28-05-2022	

	Pharmacological Group	Narcotic Analgesic
	Type of Form	Form-5
	Finished product Specification	USP specification.
	Pack size & Demanded Price	Ampoule of 5 ml, As per DPC
	Approval status of product in Reference Regulatory Authorities	Fentanyl 50 microgram/ml Injection by M/s Hameln Pharmaceuticals Ltd, MHRA approved
	Me-too status	Fentra Injection by M/s Brookes (Reg#061402)
	GMP status	DML renewal inspection conducted on 26-10-2021 & 29-10-2021 and panel recommended renewal of DML for following sections, Tablet (general) , Tablet (quinolone), Oral Liquid , Capsule (general) , Sachet , Capsule (ceph) ,Dry Powder Suspension (ceph),Topical (cream/ointment, lotion and gel) , Dry Powder Injection(ceph) , Injection ampoule (general) , Vial Infusion , Eye/Ear/Nose Drops (New),Capsule (steroid) (new, revised).
	Remarks of the Evaluator	Firm has submitted letter vide R&I dairy No 22871 dated 12-08-2022 along with revised master formulation and Form -5 along with fee challan of 30000/= vide challan no 55412351423 with following revised composition: Each 5 ml Contains Fentanyl Citrate as Fentanyl……...0.05 mg/ml (USP specifications)
	Decision: Deferred for evidence of approval of required manufacturing facility of "Tablet Psychotropic section" from Cnetral Licensing Board.	
733.	Name and address of manufacturer/ Applicant	Star Laboratories (Pvt) Ltd, 23 Km Multan Road Lahore.
	Brand Name + Dosage Form + Strength	MOXISTAR Tablet 400 mg
	Composition	Each film coated tablet contains: Moxifloxacin as Hcl……400 mg
	Diary No. Date of R & I & fee	Dy. No.162dated 07-08-2016; Rs.20,000/- dated 08-08-2016. **Duplicate Dossier** Dy. No 26776 dated 27-09-2021
	Pharmacological Group	quinolones
	Type of Form	Form-5
	Finished product Specification	Innovators specification
	Pack size & Demanded Price	1*5's
	Approval status of product in Reference Regulatory Authorities	AVELOX (moxifloxacin as hydrochloride) 400mg tablets, film coated. USFDA approved
	Me-too status	Moxizyan 400mg Tablets, film-coated. Reg. No. 77252
	GMP status	GMP certificate issued on 20-07-2020 on the basis on inspection conducted on 24-01-2020
	Remarks of the Evaluator	Monograph is present in USP.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration BoardDecision.The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
734.	Name and address of manufacturer/ Applicant	Lahore Chemical and Pharmaceuticals Works (Pvt) Ltd.137 Shahrah Moulana Jalaludin Roomi Road.
	Brand Name + Dosage Form + Strength	RETANE Eye Drops
	Composition	Cantinas: Polyethylene glycol (400) …….0.4% Propylene glycol……0.3 %
	Diary No. Date of R & I & fee	Dy. No.3354 dated 24-01-2019; Rs.20,000/- dated 23-01-2019. **Duplicate Dossier** Dy. No 10468 dated 25-04-2022
	Pharmacological Group	Lubricant
	Type of Form	Form-5
	Finished product Specification	LCPW Specs.
	Pack size & Demanded Price	375/15 ml, LDPE bottle.

	Approval status of product in Reference Regulatory Authorities	Systane of Alcon, UK, OTC product (Daily Med)	
	Me-too status	Corniwet Eye Solution,076375, Medicaids (Pvt) Ltd., Plot No 10 Sector 37 Korangi Industrial Area Karachi.	
	GMP status	GMP certificate issued on 18-10-2019 based on GMP inspection conducted on 19-09-2019	
	Remarks of the Evaluator	• Per ml Composition is not provided in form-5 • Pack size and container details not provided in form-5 • Master Formulation along with quantities of each ingredient is not provided.	Firm has submitted reply with fee challan of 7500/= vide challan No.7015760239 dated 05-08-2022 along with revised master formulation and form-5 mentioning composition as under, Each ml contains: Polyethylene glycol (400) ……...…….4 mg Propylene glycol…….3 mg
	Decision: Approved with innovators specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board		
735.	Name and address of manufacturer/ Applicant	Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road, Rawalpindi.	
	Brand Name + Dosage Form + Strength	THISTLE Tablet 200 mg	
	Composition	Each Tablet Contains: Silymarin…….200 mg	
	Diary No. Date of R & I & fee	Dy. No.1280 dated 06-10-2016; Rs.20,000/- dated 06-10-2016. **Duplicate Dossier** Dy. No 32412 dated 29-11-2021	
	Pharmacological Group	Supportive therapy for liver diseases	
	Type of Form	Form-5	
	Finished product Specification	USP	
	Pack size & Demanded Price	20'sAs per SRO	
	Approval status of product in Reference Regulatory Authorities	Not provided	
	Me-too status	Silliver 200 mg Tablets, 023930, Abbott Laboratories (Pakistan) Ltd.	
	GMP status	Not provided	
	Remarks of the Evaluator	• Form -5 does not mention as film coated tablet, however master formulation and manufacturing method outline do mention film coating. Revise Form 5 with label claim as fil coat • GMP inspection /certificate within last 3 years not provided. • Section approval letter form CLB not provided. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting		
736.	Name and address of manufacturer/ Applicant	Sigma Pharma International (Pvt) Ltd. Plot No.E-50 ,North Westren Industrial Zone , Port Qasim, Karachi	
	Brand Name + Dosage Form + Strength	SIXIL Vaginal Cream 2 %	
	Composition	Each Gram Contains: Clindamycin as Phosphate …….20 mg (2%w/w)	
	Diary No. Date of R & I & fee	Dy. No.3412 dated 15-10-2018; Rs.20,000/- dated 15-10-2018. **Duplicate Dossier** Dy. No 9327 dated 12-04-2022	
	Pharmacological Group	Antibiotic	
	Type of Form	Form-5	
	Finished product Specification	USP	
	Pack size & Demanded Price	20g,40g, As per DPC	

	Approval status of product in Reference Regulatory Authorities	Dalacin Cream 2% MHRA approved	
	Me-too status	Clindacef-V Vaginal Cream 2% w/w by M/s Roryan Pharmaceutical (Reg#096939)	
	GMP status	DML renewal inspection conducted on 12-08-2020	
	Remarks of the Evaluator	• Master formulation is not provided. • Form -5 Annexures should be dully signed /stamped.	Firm has submitted reply along with revised Form-5 dully signed along with master formulation.Firm has submitted fee challan of 30000/= vide slip No.3627357150 dated 30-08-2022
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board		
737.	Name and address of manufacturer/ Applicant	Al-Fazal Pharma (Pvt), Plot 20,21,22 Defense Industrial zone, moman Pura ,16-Km Sheikhupura, Lahore.	
	Brand Name + Dosage Form + Strength	CLINDACIN T Lotion 1 %	
	Composition	Each ml Contains: Clindamycin as Phosphate …….10 mg	
	Diary No. Date of R & I & fee	Dy. No.4912 dated 06-06-2017; Rs.20,000/- dated 06-06-2017. **Duplicate Dossier** Dy. No 6074 dated 04-04-2022	
	Pharmacological Group	Antibiotic	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer	
	Pack size & Demanded Price	30 ml, As per DPC	
	Approval status of product in Reference Regulatory Authorities	CLEOCIN T Topical Lotion USFDA approved	
	Me-too status	CDX-T T 1% Lotion by M/s Fresh Pharmaceutical (Reg#099902)	
	GMP status	Not provided	
	Remarks of the Evaluator	• Form -5 Annexures should be dully signed /stamped. • Finished product specification as per USP. • Lotion section approval from CLB. • GMP inspection/certificate within last 3 years.	• Firm has submitted vide dairy No. 24073 dated 25-08-2022 along with form-5 dully singed (Undertaking at end is missing) with Finished product as USP specification and Copy of DML renewal inspection conducted on 29-01-2022 and recommended renewal of DML for following section (a) Oral Liquid general (b) Capsule General (c) Cream/ointment/Gel General
	• **Decision: Approved with BP specifications The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
738.	Name and address of manufacturer/ Applicant	Zakfas Pharmaceuticals (Pvt) Ltd. 12-Km, Lutafabad Bosan Road,Multan.	
	Brand Name + Dosage Form + Strength	NUTRIZAK Bolus	
	Composition	Each Bolus Contains: Vitamin A……...5000IU Vitamin D3……12500IU Vitamin E……..……..25 mg Vitamin C……..……..…62.5 mg	

		Vitamin B1……..5 mg Vitamin B2……..11.5 mg Vitamin b6……..……..…...6.25 mg Biotin……...…....27.5 Nicotinamide……...…….62.5 mg Calcium D Pantothenate……..……..18.75 mg Folic Acid…….……..1.25 mg Vitamin K3……7.1 mg DL-Methionine…….25 mg L-Lysin…….12.25 mg Potassium Chloride……75 mg Manganese Sulphate …….37.5 mg Zinc Sulphate…….37.5 mg Sodium Sulphate……..…….12.5 mg Copper Sulphate……..……..5 mg Ferrous Sulphate……..……..37.5 mg
	Diary No. Date of R & I & fee	Dy. No.44(R&I) dated 21-01-2015; Rs.20,000/- dated 20-01-2015, **DUPLICATE DOSSIER** Dy.No.12072(R&I) dated 18-05-2022.
	Pharmacological Group	Vitamins & Minerals.
	Type of Form	Form-5
	Finished product Specification	Inhouse method
	Pack size & Demanded Price	50 bolus,100 bolus.
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Farvisol Bolus, 075639, Prix Pharmaceutica (Pvt) Ltd., Plot No. 5 Pharmacity 30-Km Multan Road Lahore., Lahore, Pakistan, Pakistan
	GMP status	DML renewal inspection has been conducted on 15-06-2021 and panel recommended approval of newly upgrade(revised) Bolus section (Vet) and renewal of DML.
	Remarks of the Evaluator	
	Decision:Approved with innovator specification. The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012-B&A/DRAP dated 13-07-2021. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration BoardDecision	
739.	Name and address of manufacturer/ Applicant	Ephram Labortories ,A-40,Road No 01, S.I.T.E,Super Highway Industrial Area , North Karachi .
	Brand Name + Dosage Form + Strength	MONFUSI Cream 2 %
	Composition	Each Gram Contains: Fusidic Acid…….20 mg
	Diary No. Date of R & I & fee	Dy. No.19712 dated 01-11-2017; Rs.20,000/- dated 31-10-2017. **Duplicate Dossier** Dy. No 29152 dated 26-10-2021
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	B.P specification
	Pack size & Demanded Price	5 gm, 15 gm , 20 gm , As per SRO
	Approval status of product in Reference Regulatory Authorities	Fucidin (fusidic acid) 20mg/g cream MHRA Approved
	Me-too status	Fusinax-A Cream 2%w/w by M/s Winbrain Research Laboratories (Reg# 082537)
	GMP status	GMP within last 3 years not provided
	Remarks of the Evaluator	GMP inspection/certificate within last 3 years is required. Section approval letter from CLB.

	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. The firm shall submit latest GMP inspection report conducted within last three years.	
740.	Name and address of manufacturer/ Applicant	Ephram Labortories ,A-40,Road No 01, S.I.T.E,Super Highway Industrial Area , North Karachi .
	Brand Name + Dosage Form + Strength	NAPHATE Ophthalmic Solution
	Composition	Each ml contains: Naphazoline Hydrochloride…….0.25 mg Pheniramine Maleate…….3.0 mg
	Diary No. Date of R & I & fee	Dy. No.17992 dated 12-10-2017; Rs.20,000/- dated 12-10-2017. **Duplicate Dossier** Dy. No 29153 dated 26-10-2021
	Pharmacological Group	Decongestant and Antihistamine
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10 ml, 15 ml, AS per SRO
	Approval status of product in Reference Regulatory Authorities	Naphcon-A by Alkon (USFDA)
	Me-too status	Ocucon-A Eye Drops Farmigea (Reg # 026351)
	GMP status	GMP within last 3 years not provided
	Remarks of the Evaluator	GMP inspection/certificate within last 3 years is required. Section approval letter from CLB.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. The firm shall submit latest GMP inspection report conducted within last three years.	
741.	Name and address of manufacturer/ Applicant	High Q Pharmaceuticals, B64, KDA, Karsaz Road, Karachi
	Brand Name + Dosage Form + Strength	EPRION Tablet 50 mg
	Composition	Each Tablet Contains: Eprisone Hydrochloride…….50 mg
	Diary No. Date of R & I & fee	Dy. No.41492 dated 07-12-2018; Rs.20,000/- dated 07-12-2018. **Duplicate Dossier** Dy. No 21633 dated 09-10-2021
	Pharmacological Group	Muscle relaxanat
	Type of Form	Form-5
	Finished product Specification	Japanese Pharmacopoeia
	Pack size & Demanded Price	10's,20's,30's,100's
	Approval status of product in Reference Regulatory Authorities	Expose 50mg film coated tablet, AIFA approved.
	Me-too status	Perispa 50mg tablets, Platinum pharma, Reg. No. 039302.
	GMP status	GMP within last 3 years not provided
	Remarks of the Evaluator	• GMP inspection/certificate within last 3 years is required • Firm has claimed "Eprisone" instead on "Eperisone" moreover the reference product is film coated, where as applied product is not film coated nor coating is mentioned in master formulation and manufacturing method.
	Decision: Approved as per following label claim: **Each film coated Tablet Contains:** **Eprisone Hydrochloride…….50 mg** **Registration Board further decided that registration letter will be issued upon submission of following:** • **Verification fee challan as per decision of 285th meeting of Registration Board.** • **The firm shall submit latest GMP inspection report conducted within last three years.** • **The firm shall submit preregistration variation fee challan of 7500/- along with revised master formulation and manufacturing method for uncoated tablet.**	

742.	Name and address of manufacturer/ Applicant	High Q Pharmaceuticals, B64, KDA, Karsaz Road, Karachi
	Brand Name + Dosage Form + Strength	EZOLIN Tablet 600 mg
	Composition	Each Film Coated Tablet Contains: Linezolid……600 mg
	Diary No. Date of R & I & fee	Dy. No.279 dated 18-09-2014; Rs. 20,000/- dated 18-09-2014. **Duplicate Dossier** Dy. No 21633-D dated 09-10-2021
	Pharmacological Group	Synthetic, Antibacterial, Oxazolidinones
	Type of Form	Form-5
	Finished product Specification	High-Q specification
	Pack size & Demanded Price	10's,12's,
	Approval status of product in Reference Regulatory Authorities	Zyvox 600 mg tablet by Pharmacia and Upjohn Pharma (USFDA)
	Me-too status	Ecasil by M/s Sami Pharma ,Khi
	GMP status	GMP within last 3 years not provided
	Remarks of the Evaluator	• Copy of last inspection report conducted on 10-08-2022 recommends good level of compliance. • Innovator Specification.
	Decision: Approved with innovator specifications. Registration Board further decided that registration letter will be issued upon verification of fee challan as per decision of 285th meeting of Registration Board and submission of fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
743.	Name and address of manufacturer/ Applicant	High Q Pharmaceuticals, B64, KDA, Karsaz Road, Karachi
	Brand Name + Dosage Form + Strength	TOPRAX Tablet 100 mg
	Composition	Each Film Coated Tablet Contains: Topiramate…….100 mg
	Diary No. Date of R & I & fee	Dy. No.283 dated 18-09-2014; Rs.20,000/- dated 18-09-2014. **Duplicate Dossier** Dy. No 21633-H dated 09-10-2021
	Pharmacological Group	Sulphamate
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	30's.60's
	Approval status of product in Reference Regulatory Authorities	MHRA Approved (Topiramate 100,25,50,200) as film coated tablet
	Me-too status	Tic-g 100mg Tablet of M/s. Genix Pharma (Reg.no.055677)
	GMP status	GMP within last 3 years not provided
	Remarks of the Evaluator	• Copy of last inspection report conducted on 10-08-2022 recommends good level of compliance. • Submitted labeling samples mentioned Manufacturer specifications.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.The firm shall submit pre-registration variation fee challan of 7500/=.as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021.	
744.	Name and address of manufacturer/ Applicant	High Q Pharmaceuticals, B64, KDA, Karsaz Road, Karachi
	Brand Name + Dosage Form + Strength	AMIDOX Tablet
	Composition	Each SR(Sustain Release) Tablet Contains: Doxylamine Succinate……10 mg Pyridoxamine……..10 mg
	Diary No. Date of R & I & fee	Dy. No.15719 dated 20-09-2017; Rs.20,000/- dated 20-09-2017. **Duplicate Dossier** Dy. No 21633-J dated 09-10-2021
	Pharmacological Group	Antihistamine and Vitamin B (Antiemetic)

	Type of Form	Form-5
	Finished product Specification	High-Q specification
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Doxylamine Succinate And Pyridoxine Hydrochloride (10/10) | ANDA #205811 | Tablet, Delayed Release;Oral | Prescription | Actavis Labs Fl Inc. Approved in USFDA
	Me-too status	Femiroz Tablet by M/s Efroze (Reg#061026)
	GMP status	GMP within last 3 years not provided
	Remarks of the Evaluator	• GMP inspection/certificate within last 3 years is required. • Submitted labeling samples mentioned Manufacturer specifications.
	Decision: Approved with innovator specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. The firm shall submit pre-registration variation fee challan of 7500/=as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021.	
745.	Name and address of manufacturer/ Applicant	High Q Pharmaceuticals, B64, KDA, Karsaz Road, Karachi
	Brand Name + Dosage Form + Strength	SILDOMET Tablet 50/850 mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Sitagliptin Phosphate monohydrate…50 mg Metformin Hcl……..850 mg
	Diary No. Date of R & I & fee	Dy. No.41 dated 03-11-2016, Rs.20,000/- dated 31-10-2016. **Duplicate Dossier** Dy. No 21633-I dated 09-10-2021
	Pharmacological Group	DPP-4 Inhibitor and Biguanide, Antidiabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification.
	Pack size & Demanded Price	14's.28's,30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Velmetia 50/850mg film coated tablet, Australia.
	Me-too status	S-gliptin plus. Reg # 081619
	GMP status	GMP within last 3 years not provided
	Remarks of the Evaluator	• GMP inspection/certificate within last 3 years is required. • Firm has submitted Master formulation mentioning methylene chloride in coating material, revised master formulation and manufacturing method without methylene chloride.
	Decision: Approved with innovators specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. The firm shall submit pre-registration variation fee challan of 7500/=as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021.	
746.	Name and address of manufacturer/ Applicant	Welwrd Pharmaceuticals Plot no.3, Block A, Phase III, Industrial Estate Hattar, Pakistan.
	Brand Name + Dosage Form + Strength	THIOWALT Injection 4mg/2ml
	Composition	Each Ampoule of 2 ml Contains: Thiocolchicoside…….4 mg
	Diary No. Date of R & I & fee	Dy. No.41 dated 03-11-2016, Rs.20,000/- dated 31-10-2016. **Duplicate Dossier** Dy. No 21633-I dated 09-10-2021
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COLTRAMYL 4mg/2ml, solution for injection IM in ampoule.ANSM approved
	Me-too status	Takeze 4mg/2ml Injection by M/s Shaigan Pharmaceutical (Reg#084355)
	GMP status	12-11-2018. Overall the firm is GMP compliant.

	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
747.	Name and address of manufacturer/ Applicant	Brookes Pharma (Private) Limited, 58 & 59, Sector 15, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	LAMADOL SR Tablet 100 mg
	Composition	Each Sustain Release Tablet Contains: Tramadol Hydrochloride…… 100 mg
	Diary No. Date of R & I & fee	Dy. No.41 dated 03-11-2016, Rs.20,000/- dated 31-10-2016. **Duplicate Dossier** Dy. No 21633-I dated 09-10-2021
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved as extended release tablet.
	Me-too status	Neromal ER Tablet 100mg,092941, Nabiqasim Industries (Pvt) Ltd.,Karachi
	GMP status	GMP inspection dated 11-10-2017 and 16-10-2017 concluded that the firm is considered to be operating at satisfactory level of compliance.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
748.	Name and address of manufacturer/ Applicant	Epla Laboratories, D-12, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	OSNO-D Tablet
	Composition	Each Film Coated Tablet Contains: Ossein Mineral Complex……830 mg Vitamin D……400 IU
	Diary No. Date of R & I & fee	Dy. No.41 dated 03-11-2016, Rs.20,000/- dated 31-10-2016. **Duplicate Dossier** Dy. No 21633-I dated 09-10-2021
	Pharmacological Group	Calcium Supplement
	Type of Form	Form-5
	Finished product Specification	Inhouse Specification
	Pack size & Demanded Price	6*5's, As per DPC
	Approval status of product in Reference Regulatory Authorities	Wellese Calcium and Vitamin D3 Tablet by Botanical Laboratories, USA.
	Me-too status	Bonmin Tablet by M/s. S J & G Fazal Elahi, Karachi.
	GMP status	Last GMP inspection was conducted on 11-05-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator	Methylene chaloride in coating, Form-5 Undertaking Facility of Atomic absorption and complete composition of ossein Mineral Complex is required.
	Decision: Deferred for following: • **Submissin of detailed compositionof ossein mineral complex.** • **Revised formulation of coating free from methylene chaloride.** • **Form-5 Undertaking is required.** • **Evidence of availability of Atomic absorption spectrophotometer..**	
749.	Name and address of manufacturer/ Applicant	Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form + Strength	RAZOLID Dry Suspension
	Composition	Each 5 ml Contains: Linezolid……100 mg

	Diary No. Date of R & I & fee	Dy. No.41 dated 03-11-2016, Rs.20,000/- dated 31-10-2016. **Duplicate Dossier** Dy. No 21633-I dated 09-10-2021
	Pharmacological Group	Oxazolidinones Antibiotic
	Type of Form	Form-5
	Finished product Specification	R.Poshi Specification
	Pack size & Demanded Price	60ml , as per sro
	Approval status of product in Reference Regulatory Authorities	ZYVOX (100mg/5ml) for oral suspension USFDA Approved
	Me-too status	Nezo 100mg/5ml Dry Suspension by M/s Rotex Pharma (Reg#097440)
	GMP status	Inspection date 19/09/2018, The panel recommended issuance of GMP certificate.
	Remarks of the Evaluator	
	Decision: Approved with innovator specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. The firm shall submit valid GMP certificate/inspection report before issuance of registration letter. The firm shall submit pre-registration variation fee challan of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021.	

B. Registration applications Human (New): -

(C) M/s Rotex Pharma (Pvt.) Ltd. Plot No.206-207, Industrial Triangle,Kahuta Road,Islamabad.

CLB in its 179th meeting held on 18th February 2021 has considered and approved the grant the following additional/amended sections of M/s Rotex Pharma (Pvt.) Ltd. Plot No.206-207, Industrial Triangle,Kahuta Road, Islamabad under DML No.000651 (Formulation):-

1- Gel (Preparation & filling) New Additional/Amended Section

In 317th meeting of DRP following cases were presented, however one product file was not traceable in PEC, Firm has submitted duplicate dossier, which is evaluated as below:

Section	**No. Of Previously Product applied considered in 317th meeting**	**No. of remaining product applied.**	**No. of Molecule previously applied considered on 317th meeting**	**No. of remaining molecule applied.**
Gel (Preparation & Filling) (Amended section)	08	01	08	01

Name and address of manufacturer/ Applicant	**Rotex Pharma (Pvt.) Ltd. Plot No.206-207, Industrial Triangle,Kahuta Road,Islamabad.**
Brand Name + Dosage Form + Strength	VOLDEN Gel 1 %
Composition	Each Gram Contains: Diclofenac Diethylamine eq to Diclofenac Sodium….10 mg
Diary No. Date of R & I & fee	Dy. No 16790 dated 07-03-2019; Rs.20,000/- dated 07-03-2019. **(Duplicate Dossier)**
Pharmacological Group	Phenylacetic Acid
Type of Form	Form-5
Finished product Specification	B. P
Pack size & Demanded Price	5gm,10gm,20gm, 50gm.As per SRO
Approval status of product in Reference Regulatory Authorities	Voltaren 1%w/w Gel (MHRA approved)
Me-too status	Voltral by GSK (Reg. # 083991)
GMP status	New section
Remarks of Evaluator	
Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	

D- New Cases Human (Import): -

750.	Name and address of Applicant	Name: Revive Healthcare Address: 503, 5th floor, Eden Hieghts,6 Main Gulberg, Jail road, Lahore

	Detail of Drug Sale License	Name: Revive Healthcare Address: 503, 5th floor, Eden Hieghts,6 Main Gulberg, Jail road, Lahore Go-down address: N/A License No: 05-352-0065-031159D Validity: 21st May 2020 Status: Distributor license in Form No. 11
	Name and address of manufacturer	United Biotech (p) Limited, Bagbania, Baddi-Nalagarh Road, District Solan(HP)-174 101,India
	Name and address of marketing authorization holder	United Biotech (p) Limited, Bagbania, Baddi-Nalagarh Road, District Solan(HP)-India
	Name of exporting country	India
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No. 13066 dated 06-03-2019
	Fee including differential fee	Rs.100000/- dated 06-03-2019 Challan No.1902056 dated: 06.03.2019
	Brand Name +Dosage Form + Strength	UNIFOLIN 100 Injection
	Composition	Each Vail Contains; Leucovorin Calcium …….100 mg/10 ml
	Finished Product Specification	USP
	Pharmacological Group	Detoxifying agent for antineoplastic treatment
	Shelf life	24 Month (2-8 C)
	Demanded Price	As per DPC
	Pack size	1's
	International availability	Not traceable
	Me-too status	Not varified
	Stability studies	Firm has submitted real-time stability data sheets conducted at $5^0C \pm 3^oC$ three industrial batches for 24 months (Shelf life 24 months) and accelerated stability data sheets conducted at $25^0C \pm 2\ ^oC$ and 65%RH ± 5%RH of three industrial batches for six months. Mfg. Date: 06-2013
	Detail of certificates attached	**legalized GMP certificate:** Certificate No: HFW-H(Drugs)427/05 Certifying Authority: State Drugs Controller, Controlling Cum Licensing Authority Nagar panchayat Bhawan, Sai road baddl dist,Solan. **Scan copy of legalized DML.** Serial: Not Provided **Original legalized CoPP (Embassy attested).** Certificate No: **HFW-H9(DRUGS) 461/05/241 18-09-2019** Certificate date:22-01-2018 Certifying Authority: Office of State Drugs Controller, Licensing Authority Cum Controlling Authority Health & family welfare Department, Himachal Pradesh, India Validity: 18-09-2019 **legalized Free sale Certificate.** Certificate No: HFW-H(DRUGS)/427/09 Certifying Authority: State Drugs Controller, Licensing Authority Cum Controlling Authority, Baddi, District - Solan (HP) Issuing Date: 21-11-2017 **Agency Agreement (Copy)** Between Revive Healthcare, 503, 5th floor, Eden Hieghts,6 Main Gulberg, Jail road, Lahore. (Distributor) and United

		BioTech (P) Limited, E-142, aket, New Dehli 110017. India. **Date of Agreement:** 01-03-2012 **Validity:** Complete agreement mentioning validity is not provided.
	Remark of the Evaluator [XVI]	1. DML (copy) is not provided. 2. Firm has conducted Accelerated stability study for 3 batch at 65 % RH, where as recommended Relative Humidity is 60 % for accelerated stability study. 3. Original legalized (Embassy attested) CoPP is missing. Copy is provided which is also expired. 4. Legalized copy of GMP certificate is missing, Photocopy is provided valid up to 18-09-2019. 5. Complete Agency /Exclusive distribution agreement mentioning validity is not provided. 6. DSL expired. 7. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. 8. Form 5-A mentioning "UNIFOLIN(Leucovorin) Injection 50 mg, where in attached annexures the composition as label claim is Each Vial Contains Leucovorin calcium Injection 100 mg/10 ml. 9. evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. 10. Product label does not have" URDU "Inscription as required under drug labeling and packaging rule 1978.
	Decision: Deferred for following shortcomings: **1. DSL (copy) is not provided.** **2. Firm has conducted Accelerated stability study for 3 batch at 65 % RH, where as recommended Relative Humidity is 60 % for accelerated stability study.** **3. Original legalized (Embassy attested) CoPP is missing. Copy is provided which is also expired.** **4. Legalized copy of GMP certificate is missing, Photocopy is provided valid up to 18-09-2019.** **5. Complete Agency /Exclusive distribution agreement mentioning validity is not provided.** **6. DSL expired.** **7. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** **8. Form 5-A mentioning "UNIFOLIN(Leucovorin) Injection 50 mg, where in attached annexures the composition as label claim is Each Vial Contains Leucovorin calcium Injection 100 mg/10 ml.** **9. evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** **10. Product label does not have" URDU "Inscription as required under drug labeling and packaging rule 1978.**	
751.	Name and address of Applicant	Name: Revive Healthcare Address: 503, 5th floor, Eden Hieghts,6 Main Gulberg, Jail road, Lahore
	Detail of Drug Sale License	Name: Revive Healthcare Address: 503, 5th floor, Eden Hieghts,6 Main Gulberg, Jail road, Lahore Go-down address: N/A License No: 05-352-0065-031159D Validity: 21st May 2020 Status: Distributor license in Form No. 11
	Name and address of manufacturer	United Biotech (p) Limited, Bagbania, Baddi-Nalagarh Road, District Solan(HP)-174 101,India
	Name and address of marketing authorization holder	United Biotech (p) Limited , Bagbania, Baddi-Nalagarh Road, District Solan(HP)-India
	Name of exporting country	India
	Type of Form	Form-5A

	Diary No. & Date of R& I	Dy. No. 13065 dated 06-03-2019
	Fee including differential fee	Rs.100000/- dated 06-03-2019 Challan No.1902057 dated: 06.03.2019
	Brand Name +Dosage Form + Strength	UNIPLATIN Injection 50 mg
	Composition	Each Vail Contains; Cisplatin …….50 mg/50ml
	Finished Product Specification	BP
	Pharmacological Group	Other antineoplastic agents (Platinum compounds)
	Shelf life	24 Month
	Demanded Price	As per DPC
	Pack size	1's * 50 ml
	International availability	Cisplatin 1 mg/ml Concentrate for solution for infusion (50ml vial) by M/s EBEWE Pharma (MHRA approved)
	Me-too status	UNISTIN 50mg vial by M/s Al- Habib Pharma (Reg#020661)
	Stability studies	Firm has submitted long term stability data sheets conducted at 25 ºC ± 2ºC and 60% RH for three industrial batches for 24 months (Shelf life 24 months) and accelerated stability data sheets conducted at 40^0C ± 2 ºC and 75%RH ± 5%RH of three industrial batches for six months. Mfg. Date: 07-2015
	Detail of certificates attached	**legalized GMP certificate:** Certificate No: HFW-H(Drugs)427/05 Certifying Authority: State Drugs Controller, Controlling Cum Licensing Authority Nagar panchayat Bhawan, Sai road baddl dist, Solan. Validity: 18-09-2019 **Scan copy of legalized DML.** Serial: Not Provided **Original legalized CoPP (Embassy attested).** Certificate No: **HFW-H(DRUGS) 461/05/231** Certificate date:22-01-2018 Certifying Authority: Office of State Drugs Controller, Licensing Authority Cum Controlling Authority Health & family welfare Department, Himachal Pradesh, India. Validity: 18-09-2019 **legalized Free sale Certificate.** Certificate No: HFW-H(DRUGS)/427/09 Certifying Authority: State Drugs Controller, Licensing Authority Cum Controlling Authority, Baddi, District - Solan (HP) Issuing Date: 21-11-2017 **Agency Agreement (Copy)** Between Revive Healthcare, 503, 5th floor, Eden Hieghts,6 Main Gulberg, Jail road, Lahore. (Distributor) and United BioTech (P) Limited, E-142, aket, New Dehli 110017. India. **Date of Agreement:** 01-03-2012 **Validity:** Complete agreement mentioning validity is not provided.
	Remark of the Evaluator [XVI]	1. DML (copy) is not provided. 2. The temperature and humidity conditions (25 ºC ± 2ºC and 60% RH) of the submitted stability study data for long term stability of 3 batches is not according to zone IV a, which needs clarification.

		3. Original legalized (Embassy attested) CoPP is missing. Copy is provided which is also expired. 4. Legalized copy of GMP certificate is missing, Photocopy is provided valid up to 18-09-2019. 5. Complete Agency /Exclusive distribution agreement mentioning validity is not provided. 6. DSL expired. 7. Label claim in firm 5A mentions 50 mg/5ml, where in attached annexure master formulation is mentioned as 50 mg/20 ml, which needs clarification.
	Decision: Deffered for following shortcomings: **1. DSL (copy) is not provided.** **2. The temperature and humidity conditions (25 ºC ± 2ºC and 60% RH) of the submitted stability study data for long term stability of 3 batches is not according to zone IV a, which needs clarification.** **3. Original legalized (Embassy attested) CoPP is missing. Copy is provided which is also expired.** **4. Legalized copy of GMP certificate is missing, Photocopy is provided valid up to 18-09-2019.** **5. Complete Agency /Exclusive distribution agreement mentioning validity is not provided.** **6. DSL expired.** **7. Label claim in firm 5A mentions 50 mg/5ml, where in attached annexure master formulation is mentioned as 50 mg/20 ml, which needs clarification.**	

E- Deferred Cases Human:

752.	Name and address of manufacturer/ Applicant	Relizon Pharmaceuticals, plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	RELBROF TABLET 400 mg
	Composition	Each Film Coated Tablet Contains: Ibuprofen…….400 mg
	Diary No. Date of R & I & fee	Dy. No 12137 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's,250's As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ibuprofen 400mg Tablets by M/s AUROBINDO PHARMA Ltd , USFDA Approved
	Me-too status	Fenbro tablet of M/s Stanley Pharmaceuticals
	GMP status	GMP status/report within last 3 years not provided
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Firm has mentioned film coated tablet in some documents as well as gelatin coated tablet which needs clarification. • Firm has mentioned a material "tab-coat" in their manufacturing out line however tab-coat is not mentioned in master formulation. • Evidence of applied product in RRA and me too/generic in Pakistan as gelatin coated tablets or revise formulation along fee challan. • GMP inspection report conducted within last 3 years is not provided.
	Previous Decision 317th meeting: Deferred for following shortcomings; 1. Firm has mentioned film coated tablet in some documents as well as gelatin coated tablet which needs clarification. 2. Firm has mentioned a material "tab-coat" in their manufacturing out line however tab-coat is not mentioned in master formulation. 3. Evidence of applied product in RRA and me too/generic in Pakistan as gelatin coated tablets or revise formulation along fee challan. 4. GMP inspection report conducted within last 3 years is not provided.	

	5. Preregistration variation fee challan.	
	Reply of the Firm: • This is Film Coated Tablet and Gelatin was written mistakenly. • Fee Challan No.356326580 dated 16-06-2022 of 7500/= is submitted. • Firm has submitted revised Master formulation mentioning "Tab Coat" as part of coating materials. • Firm has submitted copy of GMP inspection report Conducted on 07-06-2022 which concluded as "Keeping in the View of the Observations ~~made on the day of inspection~~ and after going through the documentations and overall operations, the panel was of the opinion that the firm M/s Relizone Pharmaceuticals,plot No.118,sunder Industrial estate Lahore was GMP compliant on the day of inspection.	
	Remarks of Evaluator	
	Decision: Approved as film coated tablet with USP specifications.	
753.	Name and address of manufacturer/ Applicant	Relizon Pharmaceuticals, plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	RELBROF TABLET 200 mg
	Composition	Each Film Coated Tablet Contains: Ibuprofen…….200 mg
	Diary No. Date of R & I & fee	Dy. No 12136 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's,250's, as per SRO.
	Approval status of product in Reference Regulatory Authorities	Brufen 200mg film coated tablets (MHRA Approved)
	Me-too status	Ibumed 200mg tablets, 074799, Medley Pharmaceuticals, 41/A Punjab Small Industries Estate Jhang Bahtar Road Wah Cantt., Wah Cantonment, Pakistan
	GMP status	GMP status/report within last 3 years not provided
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Composition of coating material "TabCoat" is not provide for film coating. • GMP inspection report conducted within last 3 years is not provided. Preregistration variation fee challan.
	Previous Decision 317th meeting: Deferred for following shortcomings; 1. Composition of coating material "TabCoat" is not provide in master formulation for film coating. 2. GMP inspection report conducted within last 3 years is not provided. 3. Preregistration variation fee challan.	
	Reply of the Firm: • This is Film Coated Tablet and Gelatin was written mistakenly. • Fee Challan No.1493564291 dated 16-06-2022 of 7500/= is submitted. • Firm has submitted revised Master formulation mentioning "Tab Coat" as part of coating materials. • Firm has submitted copy of GMP inspection report Conducted on 07-06-2022 which concluded as "Keeping in the View of the Observations and after going through the documentations and overall operations, the panel was of the opinion that the firm M/s Relizone Pharmaceuticals,plot No.118,sunder Industrial estate Lahore was GMP compliant on the day of inspection.	
	Remarks of Evaluator	
	Decision: Approved as film coated tablet with USP specifications.	
754.	Name and address of manufacturer/ Applicant	Relizon Pharmaceuticals, plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	RELFEN Tablet 500 mg
	Composition	Each Film Coated Tablet Contains: Mefenamic Acid……500 mg
	Diary No. Date of R & I & fee	Dy. No 12138 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.

	Pharmacological Group	Anti-inflammatory, Analgesic
	Type of Form	Form-5
	Finished product Specification	B.P specifications
	Pack size & Demanded Price	100's,200's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ponston SF 500 by chemidex (MHRA)
	Me-too status	Amic by Libra
	GMP status	GMP status/report within last 3 years not provided.
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Firm has mentioned as Film coted tablet however master formulation and manufacturing method does not depict film coating, submit revised master formulation and manufacturing method with preregistration variation fee. • GMP inspection report conducted within last 3 years is not provided.
	Previous Decision 317th meeting: Deferred for following followings; 1. Firm has mentioned as Film coted tablet however master formulation and manufacturing method does not depict film coating, submit revised master formulation and manufacturing method with preregistration variation fee. 2. GMP inspection report conducted within last 3 years is not provided.	
	Reply of the Firm: • Fee Challan No.57518881111 dated 16-06-2022 of 7500/= is submitted. • Firm has submitted revised Master formulation mentioning label claim of tablet without coating. • Firm has submitted copy of GMP inspection report Conducted on 07-06-2022 which concluded as "Keeping in the View of the Observations and after going through the documentations and overall operations, the panel was of the opinion that the firm M/s Relizone Pharmaceuticals,plot No.118,sunder Industrial estate Lahore was GMP compliant on the day of inspection.	
	Remarks of Evaluator	
	Decision: Approved.	
755.	Name and address of manufacturer/ Applicant	Relizon Pharmaceuticals, plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	LEZIR Tablet 10 mg
	Composition	Each Film Coated Tablet Contains: Cetirizine Hydrochloride……..…10 mg
	Diary No. Date of R & I & fee	Dy. No 12141 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Histamine H1 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	B.P specifications
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA. Zirtek 10mg film coated tablet
	Me-too status	Serzine 10mg Tablets, Qintar Pharma, Reg. No. 030644.
	GMP status	GMP status/report within last 3 years not provided.
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Firm-5 Cover letter is not signed. Submit revised signed Form-5 cover letter with pre-registration variation fee. GMP inspection report conducted within last 3 years is not provided.
	Previous Decision 317th meeting: Deferred for following followings; 1. Firm-5 Cover letter is not signed. Submit revised signed Form-5 cover letter with pre-registration variation fee. 2. GMP inspection report conducted within last 3 years is not provided**.**	
	Reply of the Firm: • Fee Challan No.22118644523 dated 16-06-2022 of 7500/= is submitted. • Firm has submitted signed form-5 along with annexure. • Firm has submitted copy of GMP inspection report Conducted on 07-06-2022 which concluded as "Keeping in the View of the Observations and after going through the documentations and	

	overall operations, the panel was of the opinion that the firm M/s Relizone Pharmaceuticals,plot No.118,sunder Industrial estate Lahore was GMP compliant on the day of inspection.	
	Remarks of Evaluator	
	Decision: Approved.	
756.	Name and address of manufacturer/ Applicant	Relizon Pharmaceuticals, plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	TRAMCET Tablet 325/37.5 mg
	Composition	Each Film Coated Tablet Contains: Paracetamol……325 mg Tramadol Hydrochloride……37.5 mg
	Diary No. Date of R & I & fee	Dy. No 12140 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Opioid Analgesic/Antipyretic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ultracet Tablet by M/s Janssen Ortho, (USFDA approved)
	Me-too status	Forgesil Tablet by M/s Genome Pharmaceutical (Reg No:080874
	GMP status	GMP status/report within last 3 years not provided.
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Firm has mentioned as Film coted tablet however master formulation and manufacturing method does not depict film coating, submit revised master formulation and manufacturing method with preregistration variation fee. • GMP inspection report conducted within last 3 years is not provided.
	Previous Decision 317th meeting: Deferred for following shortcomings; 1. Firm has mentioned as Film coted tablet however master formulation and manufacturing method does not depict film coating, submit revised master formulation and manufacturing method with preregistration variation fee. 2. GMP inspection report conducted within last 3 years is not provided.	
	Reply of the Firm: • Fee Challan No.49418968536 dated 19-05-2022 of 7500/= is submitted. • Firm has submitted revised master formulation and method of manufacturing mentioning Coating material and method. • Firm has submitted copy of GMP inspection report Conducted on 07-06-2022 which concluded as "Keeping in the View of the Observations and after going through the documentations and overall operations, the panel was of the opinion that the firm M/s Relizone Pharmaceuticals,plot No.118,sunder Industrial estate Lahore was GMP compliant on the day of inspection.	
	Remarks of Evaluator	
	Decision:Approved.	
757.	Name and address of manufacturer/ Applicant	Medipak Limited,554 sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	PANAFIN I.V Infusion (100ml)
	Composition	Each ml contains: Paracetamol……...10 mg
	Diary No. Date of R & I & fee	Dy. No 12569 dated 06-03-2019; Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Antipyretic
	Type of Form	Form - 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	100 ml, Polypropylene Bottle with Euro Cap, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved with Type I colourless glass vial with bromobutyl stopper and an aluminum /plastic flip-off cap
	Me-too status	Not provided.
	GMP status	GMP report within 3 years is required

	Remarks of the Evaluator	• GMP inspection report conducted within last 3 years is required. • Evidence of applied product in RRA in applied primary packing of Polypropylene bottle or revise formulation along with evidence of manufacturing facility and preregistration variation fee challan. • Revised master formulation as per revised label claim. • Mee-too reference of applied product with applied primary packaging in Pakistan.
	Previous Decision 317th meeting: Deferred for Following shortcomings: 1. GMP inspection report conducted within last 3 years is required. 2. Evidence of applied product in RRA in applied primary packing of Polypropylene bottle or revise formulation along with evidence of manufacturing facility and preregistration variation fee challan. 3. Revised master formulation as per revised label claim. 4. Mee-too reference of applied product with applied primary packaging in Pakistan.	
	Reply of the Firm: • Firm has submitted copy of GMP certificate issued on 29-07-2021 based on inspection conducted on 21-05-2021 for Intravenous Infusion. • Firm has submitted MHRA reference of Paracetamol 10mg/ml (1000mg/100 ml) Solution for infusion mentioning nature and contents of container as,"100 ml solution contained in 100 ml polyethylene/polyamide/polypropylene (Viaflo) plastic bags, provided with one polyethylene dummy non-accessible port and one polyethylene administration port with clear/foil over pouch."	
	Remarks of the Evaluator	• Reference /evidence of Me-Too of applied product already registered in Pakistan with Polypropylene Bottle with Euro Cap is not provided. Nor Firm has applied as new Formulation. • Application on Form 5-D with differential fee for registration of new molecule along with stability study data/comparative study with RRA product container closure system, is also not provided.
	Decision: Approved with innovators specifications. • **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
758.	Name and address of manufacturer/ Applicant	Medipak Limited,554 sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	MEDISOL MANITOL I.V Infusion (500ml)
	Composition	Each 1000 ml contains: Mannitol …….175 g Sorbitol……. …….25 g Water for Injection…….1000 ml
	Diary No. Date of R & I & fee	Dy. No 12566 dated 06-03-2019; Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Osmotic Diuretic
	Type of Form	Form - 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	500 ml, Polypropylene Bottle with Euro Cap, As per SRO
	Approval status of product in Reference Regulatory Authorities	Not provided
	Me-too status	Not provided
	GMP status	GMP report within 3 years is required
	Remarks of the Evaluator	1. GMP inspection report conducted within last 3 years is required. 2. Label claim and master formulation mentioned water for injection 1000 ml instead of whereas applied pack size is 500 ml, clarification is needed

		3. Evidence of applied product in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan. 4. Revised master formulation as per revised label claim. 5. Mee-too reference of applied product with applied primary packaging in Pakistan.
	Previous Decision 317th meeting: Deferred for Following shortcomings: 1. GMP inspection report conducted within last 3 years is required. 2. Label claim and master formulation mentioned water for injection 1000 ml instead of whereas applied pack size is 500 ml, clarification is needed 3. Evidence of applied product containing Glucose anhydrous in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan. 4. Revised master formulation as per revised label claim. 5. Mee-too reference of applied product with applied primary packaging in Pakistan.	
	Reply of the Firm: • Firm has submitted copy of GMP certificate issued on 29-07-2021 based on inspection conducted on 21-05-2021 for Intravenous Infusion. • Firm has submitted revised Form-5 along with fee challan No.20306238907 dated 06-06-2022 with revised label claim composition and formulation as "Each 100 ml Contains: Mannitol……20 gm Water for Injection …….100 ml (500 ml in Polypropylene Bottle) • Firm has also provided RRA refence of USFDA, Mannitol 20 % in Plastic Container (20 gm/100ml). pack size 500 ml. • Firm has provided me too reference of Steriflutol-20, Reg # 076884, FDL Limited.	
	Remarks of Evaluator	• The me too provided has sorbitol in composition, which is not mentioned in revised form-5, more over the mee too product, Steriflutol-20 has container closure with LDPE where as applied product container closure system is Polypropylene. • Application on Form 5-D with differential fee for registration of new molecule along with stability study data/comparative study with RRA product container closure system, is also not provided.
	Decision: Deferred for following: • **The me too provided has sorbitol in composition, which is not mentioned in revised form-5, more over the me too product, Steriflutol-20 has container closure with LDPE where as applied product container closure system is Polypropylene.** • **Application on Form 5-D with differential fee for registration of new molecule along with stability study data/comparative study with RRA product container closure system, is required.**	
759.	Name and address of manufacturer/ Applicant	Medipak Limited,554 sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	MEDISOL I.V Infusion 10 % (1000ml)
	Composition	Each 100 ml contains: Dextrose Anhydrous ……10 g Water for Injection ……...…100 ml
	Diary No. Date of R & I & fee	Dy. No 12567 dated 06-03-2019; Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Carbohydrates
	Type of Form	Form - 5
	Finished product Specification	BP specification
	Pack size & Demanded Price	1000 ml, Polypropylene Bottle with Euro Cap, As per SRO
	Approval status of product in Reference Regulatory Authorities	Not provided
	Me-too status	Not provided
	GMP status	GMP report within 3 years is required
	Remarks of the Evaluator	1. GMP inspection report conducted within last 3 years is required.

		2. Evidence of applied product containing Glucose anhydrous in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan. 3. Revised master formulation as per revised label claim. 4. Mee-too reference of applied product with applied primary packaging in Pakistan.
	Previous Decision 317th meeting: Deferred for Followings: **1. GMP inspection report conducted within last 3 years is required.** **2. Evidence of applied product containing Glucose anhydrous in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan.** **3. Revised master formulation as per revised label claim.** **4. Mee-too reference of applied product with applied primary packaging in Pakistan.**	
	Reply of the Firm: • Firm has submitted copy of GMP certificate issued on 29-07-2021 based on inspection conducted on 21-05-2021 for Intravenous Infusion. • **Firm has also provided RRA refence of USFDA, Dextrose 10 % in Plastic Container (100gm/100ml). Pack Size not mentioned.** • **Firm has provided me too reference of Steriflutol, Reg # 049819, FDL Limited.**	
	Remarks of Evaluator	• The me- too product, Steriflutol-20 has container closure with LDPE where as applied product container closure system is Polypropylene. • USFDA in label has described that the plastic container is made from a multilayered film specifically developed for parenteral drugs. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during use. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary. • Application on Form 5-D with differential fee for registration of new molecule along with stability study data/comparative study with RRA product container closure system, is also not provided.
	Decision: Deferred for further deliberation regarding container closure system of applied product, already approved generic and RRA approved products.	
760.	Name and address of manufacturer/ Applicant	Medipak Limited,554 sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	MEDISOL I.V Infusion 10 % (500ml)
	Composition	Each 100 ml contains: Dextrose Anhydrous …….10 g Water for Injection ……...…100 ml
	Diary No. Date of R & I & fee	Dy. No 12568 dated 06-03-2019; Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Carbohydrates
	Type of Form	Form - 5
	Finished product Specification	BP specification
	Pack size & Demanded Price	500 ml, Polypropylene Bottle with Euro Cap, As per SRO
	Approval status of product in Reference Regulatory Authorities	Not provided
	Me-too status	Not provided
	GMP status	GMP report within 3 years is required
	Remarks of the Evaluator	1. GMP inspection report conducted within last 3 years is required. 2. Evidence of applied product containing Glucose anhydrous in RRA in applied primary packing of

		Polypropylene bottle or revise formulation along fee challan. 3. Revised mate formulation as per revised label claim. 4. Mee-too reference of applied product with applied primary packaging in Pakistan.	
	Previous Decision 317th meeting: Deferred for Followings: 1. GMP inspection report conducted within last 3 years is required. 2. Evidence of applied product containing Glucose anhydrous in RRA in applied primary packing of Polypropylene bottle or revise formulation along fee challan. 3. Revised master formulation as per revised label claim. 4. Mee-too reference of applied product with applied primary packaging in Pakistan.		
	Reply of the Firm: • Firm has submitted copy of GMP certificate issued on 29-07-2021 based on inspection conducted on 21-05-2021 for Intravenous Infusion. • Firm has also provided RRA refence of USFDA, Dextrose 10 % in Plastic Container (100gm/100ml). Pack Size not mentioned. • Firm has provided me too reference of Steriflutol, Reg # 049819, FDL Limited.		
	Remarks of Evaluator	• The me- too product, Dextrose 10 % has container closure with LDPE where as applied product container closure system is Polypropylene. • USFDA in label has described that the plastic container is made from a multilayered film specifically developed for parenteral drugs. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during use. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary. • Application on Form 5-D with differential fee for registration of new molecule along with stability study data/comparative study with RRA product container closure system, is also not provided.	
	Decision: Deferred for further deliberation regarding container closure system of applied product, already approved generic and RRA approved products.		
761.	Name and address of manufacturer/ Applicant	Cibex (Pvt) Ltd. F-405 S.I.T.E, Karachi.	
	Brand Name + Dosage Form + Strength	RHIZIN-X NASAL SPRAY 15 ml	
	Composition	Each ml of spray contains: Sodium Cromoglycate……4 % Xylometazoline……0.025 %	
	Diary No. Date of R & I & fee	Dy. No 12011 dated 06-03-2019; Rs.20,000/- dated 04-03-2019	
	Pharmacological Group	Antihistamine	
	Type of Form	Form - 5	
	Finished product Specification	Innovator's Specification.	
	Pack size & Demanded Price	1's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Not verified	
	Me-too status	Oxycrom-P Nasal Spray, Sante (Pvt)Ltd. (Not verified)	
	GMP status	GMP inspection conducted on 11/6/2021 on the basis of GMP inspection conducted 02/06/2021	
	Remarks of the Evaluator	1. Form-5 on prescribed format including the composition /label claim. 2. Manufacturing Flow chart/outline. 3. Section approval letter.	Firm has submitted revised form -5 on prescribed format with label claim as: Each ml of spray contains: Sodium Cromoglycate……4 %

		4. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. 5. In some documents firm has mentioned Xylometazoline 0.025 mg/ml and in some documents, they mentioned it as xylometazoline 0.25 mg / ml, clarify the label claim with full differentiation preregistration variation fee challan of 20000/=.	Xylometazoline…0.025 % along with annexures (master formulation and manufacturing method), along with Fee challan No. 41766043424 dated 08-03-2022 of 7500/=.
	Previous Decision 316th meeting: Deferred for following; • Confirmation of required manufacturing facility / section from Licensing Division. • The firm shall submit full differential fee of 22500/= for submission of revised Form-5 on prescribed format as per SRO No. F.7-11/2012-B&A/DRAP dated 13-07-2021.		
	Reply of the Firm: Firm has submitted differential fee challan No.918407119119 dated 28-06-2022 of 22500/= and claimed manufacturing facility of Nasal spray in topical section. (copy of approval of Topical section from CLB is attached)		
	Remarks of Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Me-too/Generic product registered in Pakistan. • Nasal spray manufacturing facility/Section from CLB	
	Decision: Deferred for following shortcomings: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Me-too/Generic product registered in Pakistan.** • **Nasal spray manufacturing facility/Section from CLB**		
762.	Name and address of manufacturer/ Applicant	Cibex (Pvt) Ltd. F-405 S.I.T.E, Karachi.	
	Brand Name + Dosage Form + Strength	RHIZIN NASAL SPRAY 15 ml	
	Composition	Each ml of spray solution contains: Sodium Cromoglycate……4 %	
	Diary No. Date of R & I & fee	Dy. No 12001 dated 06-03-2019; Rs.20,000/- dated 04-03-2019	
	Pharmacological Group	Antihistamine	
	Type of Form	Form - 5	
	Finished product Specification	USP Specification.	
	Pack size & Demanded Price	1's, As per SRO	
	Approval status of product in Reference Regulatory Authorities	Not Verified	
	Me-too status	Oxycrom-P nasal spray 15ml of M/s Sante Pakistan Ltd. (Reg.#025164)	
	GMP status	GMP inspection conducted on 11/6/2021 on the basis of GMP inspection conducted 02/06/2021	
	Remarks of the Evaluator	1. Form-5 on prescribed format including the composition /label claim. 2. Manufacturing Flow chart/outline. 3. Section approval letter.	Firm has submitted revised form -5 on prescribed format along with annexures (master formulation and manufacturing method), along with Fee challan No.

		4.Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	41766043424 dated 08-03-2022 of 7500/=
	Previous Decision 316th meeting: Deferred for following; • Confirmation of required manufacturing facility / section from Licensing Division. • The firm shall submit full differential fee of 22500/= for submission of revised		
	Reply of the Firm: Firm has submitted differential fee challan No.3848400538 dated 28-06-2022 of 22500/= and claimed manufacturing facility of Nasal spray in topical section. (copy of approval of Topical section from CLB is attached)		
	Remarks of Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Nasal spray manufacturing facility/Section from CLB	
	Decision: Deferred for following shortcomings: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Nasal spray manufacturing facility/Section from CLB**		
763.	Name and address of manufacturer/ Applicant	M/s. Shrooq Pharmacetuicals (Pvt) Ltd., 21-Km Ferozepur Road, Lahore.	
	Brand Name + Dosage Form + Strength	Occunet I.V Infusion	
	Composition	Each 250ml Contains: - Moxifloxacin (as Hydrochloride) ……..….400mg	
	Diary No. Date of R & I & fee	Dy. No 563 dated 27-3-2014, Rs.20,000/	
	Pharmacological Group	(Quinolone)	
	Type of Form	Form - 5	
	Finished product Specification	Manufacturer Specification.	
	Pack size & Demanded Price	1×250ml, As per SRO	
	Approval status of product in Reference Regulatory Authorities	BNF: Avelox (Bayer) Moxifloxacin 400mg/250mL Solution for infusion MHRA Approved.	
	Me-too status	Molox (CCL). M-Floxsel Infusion 400mg/250ml by M/s Pharmasol (Pvt) Ltd (Reg#100857)	
	GMP status	DML renewal inspection conducted on 26-10-2021 & 29-10-2021, the panel recommends the renewal of DML.	
	Previous remarks of the Evaluator	1. Firm has RW-500 vial filling Machine which has filling range of 2-100ml, However Firm claims that its range can be increase to 250ml. 2. TOC analyzer and liquid particle counter are under the process of procurement.	
	Previous Decision 245th meeting: Deferred for TOC & Liquid Particle counter. The confirmation of manufacturing facility requirement for large volume parenteral shall be sought out from directorate of Drug Licensing.		
	Reply of the Firm: Firm has submitted their reply along with last inspection report dated 26-10-2021 & 29-10-2021 for Renewal of DML, where in the panel of inspectors has mentioned on page 5 under the heading **h) Vial Infusion Section: The washing and solution area for ampoules and vials were same. Separate filling room for vial infusion was provided which was equipment with <u>vial filling and sealing machine under laminar flow hood</u>, HEPA filter. the area was maintained.** On page 6 of report under the heading **5. Laboratory Control: The quality control laboratory was divided in to chemical laboratory, instrument room and microbiology laboratory. Requisite equipment such as three HPLC, UV spectrophotometer, FTIR, <u>TOC apparatus</u>, Dissolution apparatus, <u>Liquid Particle Counter</u> e.t.c were installed.**		

	Firm has also attached approval of Vial Infusion section vide letter No. F. 6-2/2013-Lic (M-233) dated 7-4-2014 issued by CLB.	
	Remarks of Evaluator	
	Decision: Approved with innovator specification. The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012-B&A/DRAP dated 13-07-2021	

Agenda of Evaluator PEC-XVII.

Case No. 1: Registration applications for local manufacturing of (Human) drugs.

a; New cases:

764.	Name and address of manufacture / Applicant	M/s Epla Laboratories (Pvt) Ltd., D-12, Estate Avenue, S.I.T.E, Karachi.
	Brand Name + Dosage Form and Strength	CLARBACT suspension (125mg/5ml)
	Composition	Each 5ml of reconstituted suspension contains: Clarithromycin…...125mg (as taste-mask granules)
	Dairy No. date of R &I fee	Dy. No. 13054 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No. 0817936 dated: 26.02.2019
	Pharmacological Group	Macrolide antibiotic
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	60ml, as per DRAP policy/ Brand leader
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Granules for oral suspension)
	Me-too-status	Texklar 125mg/5ml Dry Suspension of Rotex pharma Islamabad. Registration No. 097435
	GMP Status	Routine GMP inspection conducted on 21-06-2022 with conclusion as: Based on the areas inspected, the people met and the documents reviewed, M/s Epla Laboratories (Pvt) Limited is considered to be operating at good level of GMP compliance as per DRAP Act, 2012 and rules framed thereunder.
	Remark of the Evaluator (PEC-XVII)	• Firm has changed taste-mask granules source from Guobang Pharmachem Group Co., Ltd. China to M/s Surge Laboratories Pvt. Ltd. Sheikhupura and submitted fee of Rs: 30,000/- vide online deposit slip No.3966850056 for source change. • Firm has provided CoA of Clarithromycin taste mask coated granules 27.5% w/w (suspension grade). • Firm has provided GMP certificate of granules manufacturer/supplier (Surge laboratories, Sheikhupura) dated 04-07-2019. • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2ºC and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data sheets conducted at 40 ^{0}C ± 2 ºC and 75%RH ± 5%RH of three batches for six months with testing

		points as 0, 3, 6, 9, 12, 18, 24 & 36 months (for Long term stability studies) and 0, 1, 2, 3 & 6 months (for Accelerated Stability Conditions). • The Dry Powder Suspension (General) Section mentioned/available vide Licensing Division, DRAP Islamabad letter No.F.2-4/2000-Lic (Vol-II) dated 20-09-2021, titles as "Renewal of Drug Manufacturing Licensing Under the Drugs Act, 1976.
	Decision: Approved.	
765.	Name and address of manufacture / Applicant	M/s Epla Laboratories (Pvt) Ltd., D-12, Estate Avenue, S.I.T.E, Karachi.
	Brand Name + Dosage Form and Strength	CLARBACT DS suspension (250mg/5ml)
	Composition	Each 5ml reconstituted suspension contains: Clarithromycin…..250mg (as taste-mask granules)
	Dairy No. date of R &I fee	Dy. No. 13053 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No. 0817937 dated: 26.02.2019
	Pharmacological Group	Macrolide antibiotic
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	60ml, as per DRAP policy/ Brand leader
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Granules for oral suspension)
	Me-too-status	Karit 250mg/5ml Dry Suspension of Saffron Pharmaceuticals, Faisalabad. Registration No. 097781
	GMP Status	Routine GMP inspection conducted on 21-06-2022 with conclusion as: Based on the areas inspected, the people met and the documents reviewed, M/s Epla Laboratories (Pvt) Limited is considered to be operating at good level of GMP compliance as per DRAP Act, 2012 and rules framed thereunder.
	Remark of the Evaluator (PEC-XVII)	• Firm has changed taste-mask granules source from Guobang Pharmachem Group Co., Ltd. China to M/s Surge Laboratories Pvt. Ltd. Sheikhupura and submitted fee of Rs: 30,000/- vide online deposit slip No.69855717275 for source change. • Firm has provided CoA of Clarithromycin taste mask coated granules 27.5% w/w (suspension grade). • Firm has provided GMP certificate of granules manufacturer/supplier (Surge laboratories, Sheikhupura) dated 04-07-2019. • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2ºC and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data sheets conducted at 40 ^{0}C ± 2 ºC and 75%RH ± 5%RH of three batches for six months with testing points as 0, 3, 6, 9, 12, 18, 24 & 36 months (for Long term stability studies) and 0, 1, 2, 3 & 6 months (for Accelerated Stability Conditions). • The Dry Powder Suspension (General) Section mentioned/available vide Licensing Division, DRAP Islamabad letter No.F.2-4/2000-Lic (Vol-II) dated 20-09-2021, titles as "Renewal of Drug Manufacturing Licensing Under the Drugs Act,

		1976.
	Decision: Approved.	
766.	Name and address of manufacturer/ Applicant	Applicant: Gillman Pharmaceuticals, Plot No.41/2-A, Phase I & II, Industrial Estate Hattar. Manufactured by: M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	TRANSAGIL 500mg/5ml injection
	Composition	Each 5ml ampoule contains: Tranexamic acid……. 500mg
	Diary No. Date of R & I & fee	Dy.No 11486 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Anti-fibrinolytic agent
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Hixamic 500mg injection, Himont Pharmaceuticals Lahore. Registration No. 047937
	GMP status	Panel inspection for renewal of DML conducted on 13-02-2019 and concluded as "Based on the area inspected, the people met, documents reviewed and considering the findings especially the efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended the renewal of Drug Manufacturing License No.000752 (by way of formulation) to M/s EG Pharmaceuticals, Plot No.13A, Industrial Triangle, Kahuta Road, Islamabad.
	Remarks of the Evaluator (PEC-XVII)	• GMP inspection report of the contract acceptor that is M/s EG Pharmaceuticals, Kahuta road, Islamabad is required. • GMP inspection report of the contract giver that is M/s Gillman Pharmaceuticals, Plot No.41/2-A, Phase I & II, Industrial Estate Hattar is required. • Method of sterilization has not been mentioned in manufacturing outlines. • Registration Board in its 288th meeting upon detailed deliberation of capacity assessment report and considering the measures taken by the firm for upgradation of QC lab decided to allow contract manufacturing by M/s EG Pharmaceuticals, Industrial Triangle Kahuta • Road, Islamabad • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. **Registration letter will be issued upon submission of following:** • **Revised manufacturing outlines with details of sterilization method employed alongwith fee of Rs. 7,500/- as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for manufacturing outlines revision** • **Latest GMP inspection report of both applicant and manufacturer conducted within last three years.**	
767.	Name and address of manufacturer/ Applicant	Applicant: Gillman Pharmaceuticals, Plot No.41/2-A, Phase I & II, Industrial Estate Hattar.

		Manufactured by: M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	SETRON 8mg/4ml injection (IM/IV)
	Composition	Each 4ml ampoule contains: Ondansetron (as Hydrochloride dihydrate) …...8mg
	Diary No. Date of R & I & fee	Dy.No 11485 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	5HT3 antagonist
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	5's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Anomed 8mg injection by Evergreen pharmaceuticals, Lahore. Registration No.069099 Vemtix 8mg/4ml Injection by M/s Biolabs Islamabad. Reg# 093252)
	GMP status	Panel inspection for renewal of DML conducted on 13-02-2019 and concluded as "Based on the area inspected, the people met, documents reviewed and considering the findings especially the efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended the renewal of Drug Manufacturing License No.000752 (by way of formulation) to M/s EG Pharmaceuticals, Plot No.13A, Industrial Triangle, Kahuta Road, Islamabad.
	Remarks of the Evaluator (PEC-XVII)	• GMP inspection report of the contract acceptor that is M/s EG Pharmaceuticals, Kahuta road, Islamabad is required. • GMP inspection report of the contract giver that is M/s Gillman Pharmaceuticals, Plot No.41/2-A, Phase I & II, Industrial Estate Hattar is required. • Weight of API is not adjusted in the master formulation considering the salt and hydrated form of the drug. • Method of sterilization has not been mentioned in manufacturing outlines. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. **Registration letter will be issued upon submission of following:** • **Revised manufacturing outlines with details of sterilization method employed alongwith fee of Rs. 7,500/- as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for manufacturing outlines revision** • **Latest GMP inspection report of both applicant and manufacturer conducted within last three years.**	
768.	Name and address of manufacture / Applicant	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore (Tablet I & II General)
	Brand Name + Dosage Form and Strength	BIOMP 40mg Tablet
	Composition	Each gastro resistant tablet contains: Omeprazole ……. 40mg
	Dairy No. date of R &I fee	Form-5 Dy. No. 10339 dated 05-03-2019 Rs.20,000 dated 04-03-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	14's, As per SRO

	Approval status of product in Reference Regulatory Authorities	Losec MUPS (multiple unit pellet system) 40mg AstraZeneca UK (MHRA approved) Omeprazole 40 mg gastro-resistant tablets Each gastro-resistant tablet contains 40 mg Omeprazole (MHRA approved
	Me-too-status	BENZIM 40mg Tablet (M/S Wilshire) Reg. # 044599
	GMP Status	GMP certificate valid till 12-02-2022, issued on the basis of inspection conducted on 13-02-2020.
	Remark of the Evaluator (PEC-XVII)	• Revision is not required since the label claim provided is in line with reference product. Submit master formulation of the product. • Revision of manufacturing outlines not required as the applied formulation is available as gastro-resistant tablet (enteric coated). For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • DML granted vide letter No. F.1-29/2011-Lic dated 12-06-2017 w.e.f 12.06.2017 for following sections: Tablet I (General) Tablet II (General) Capsule (General) Sachet (General) Oral syrup (General)
	Decision: Approved with BP specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

769.	Name and address of manufacture / Applicant	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore (Tablet I & II General)
	Brand Name + Dosage Form and Strength	NEBVAL 5/80mg tablet
	Composition	Each film-coated tablet contains: Nebivolol …. 5mg Valsartan …... 80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10331 dated 05-03-2019 Rs.20,000 dated 04-03-2019
	Pharmacological Group	Nebivolol: Beta adrenergic blocker /Anti-hypertensive Valsartan: Angiotensin Receptor Antagonists/Anti-hypertensive
	Type of form	Form 5
	Finished product specifications	Innovator specifications
	Pack size and Demand Price	14's, 30's, 60's, As per SRO
	Approval status of product in Reference RegulatoryAuthorities	BYVALSON 5mg/80mg Allergen USA (USFDA status is discontinued)
	Me-too-status	Could not be confirmed
	GMP Status	GMP certificate valid till 12-02-2022, issued on the basis of inspection conducted on 13-02-2020.

	Remark of the Evaluator (PEC-XVII)	• Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm as the "Me too" provided by the firm could not be confirmed. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting as BYVALSON 5mg/80mg Allergen USA (USFDA) status is discontinued. • DML granted vide letter No. F.1-29/2011-Lic dated 12-06-2017 w.e.f 12.06.2017 for following sections: Tablet I (General) Tablet II (General) Capsule (General) Sachet (General) Oral syrup (General)
	Decision: Deferred for following; **•Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** **•Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
770.	Name and address of manufacture / Applicant	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore (Tablet I & II General)
	Brand Name + Dosage Form and Strength	Deflu 10mg Tablet
	Composition	Each film-coated tablet contains: Loratadine…10mg
	Dairy No. date of R &I fee	Form-5 Dy. No 10851 dated 05-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Histamine H1 Antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	CLARITIN 10mg tablet (Bayer) MHRA approved
	Me-too-status	ANTIAL 10mg tablet by Sami pharmaceuticals, Karachi (Registration No. 019675)
	GMP Status	GMP certificate valid till 12-02-2022, issued on the basis of inspection conducted on 13-02-2020.
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each tablet contains: Loratadine…...10mg • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • DML granted vide letter No. F.1-29/2011-Lic dated 12-06-2017 w.e.f 12.06.2017 for following sections: Tablet I (General) Tablet II (General) Capsule (General) Sachet (General) Oral syrup (General)
	Decision: Approved with revised label claim as; **Each tablet contains:** **Loratadine…...10mg** **•Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from film-coated tablet to un-coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

771.	Name and address of manufacture / Applicant	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore (Tablet I & II General)
	Brand Name + Dosage Form and Strength	INVGA 3mg tablet
	Composition	Each sustained release tablet contains: Paliperidone…3mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10853 dated 05-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Anti-Psychotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	14's, 28's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Trilayer capsule-shaped white tablets of 11 mm in length and 5 mm in diameter printed with "PAL 3" INVEGA 3mg Janssen Inc. UK Approved MHRA (BNF p# 374-375)
	Me-too-status	VEGADON SR 3mg Danas Pharmaceuticals Reg. # 080372
	GMP Status	GMP certificate valid till 12-02-2022, issued on the basis of inspection conducted on 13-02-2020.
	Remark of the Evaluator (PEC-XVII)	• The reference product Invega, approved by USFDA is Extended release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. Provide evidence of required manufacturing technology as per reference product. • The firm has claimed USP specifications while the product is non-pharmacopoeial. • Master formulation for the applied product is required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • DML granted vide letter No. F.1-29/2011-Lic dated 12-06-2017 w.e.f 12.06.2017 for following sections: Tablet I (General) Tablet II (General) Capsule (General) Sachet (General) Oral syrup (General)
	Decision: Deferred for following; • **Evidence of availability of requisite manufacturing technology (OROS Push-Pull technology as per innovator/reference product (INVEGA 3mg).** • **Revision of finished drug product specifications as firm has claimed USP specifications, while official monograph of the product not available.** • **Submission of master formulation as per reference product.**	
772.	Name and address of manufacture / Applicant	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore (Oral Syrup General)
	Brand Name + Dosage Form and Strength	I folk 40mg/5mg
	Composition	Each 15ml Contains: Iron Protein Succinylate 800mg Eq. to Elemental Iron ……50mg Folic Acid…5mg
	Dairy No. date of R &I fee	Form-5 Dy. No 10870 dated 05-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Iron preparation
	Type of form	Form 5
	Finished product specifications	Innovator

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too-status	Sucrofer F (800mg, 5mg/15ml) syrup by M/s CCL Pharmaceuticals, Lahore. Varience HB (800mg, 5mg/15ml syrup by Unison Chemicals, Lahore. Batema-F syrup (800mg, 5mg/15ml) Cibex Pvt. Ltd. Karachi Reg # 076713
	GMP Status	GMP certificate valid till 12-02-2022, issued on the basis of inspection conducted on 13-02-2020.
	Remark of the Evaluator (PEC-XVII)	• The strength mentioned in the cover letter as "Iron protein succinylate 200mg + Folid acid 2.5mg/5ml" while in Form-5, the composition mentioned as "Each 15 ml contains Iron Protein Succinylate 800mg equivalent to elemental iron 40mg and folid acid 5mg. Furthermore, there is variation in composition in different sections of the dossier. • DML granted vide letter No. F.1-29/2011-Lic dated 12-06-2017 w.e.f 12.06.2017 for following sections: Tablet I (General) Tablet II (General) Capsule (General) Sachet (General) Oral syrup (General)
	Decision: Deferred for further deliberation regarding composition of applied product and already approved generic products.	
773.	Name and address of manufacture / Applicant	M/s Bio-Labs (Pvt) ltd., Plot No.145, Industrial Triangle, Kahuta Road, Islamabad. Capsule Section (General)
	Brand Name + Dosage Form and Strength	CHOLITOLRATE capsules 4mg
	Composition	Each prolonged-release capsule contains: Tolterodine tartrate…….4mg
	Dairy No. date of R &I fee	Dy. No 12434 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Anti-cholinergic agent
	Type of form	Form 5
	Finished product specifications	BP specifications
	Pack size and Demand Price	30's as per DRAP's pricing policy
	Approval status of product in Reference Regulatory Authorities	Detrusitol XL 4 mg, prolonged-release capsules, hard (MHRA approved)
	Me-too-status	Urot 4mg capsules by Ciba pharmaceuticals, Karachi. Registration No. 097154
	GMP Status	GMP certificate issued to firm on 21st May, 2019, on the basis of panel GMP inspection conducted on 23.04.2019 and valid upto 22.04.2022.
	Remark of the Evaluator (PEC-XVII)	• GMP inspection report conducted within last 03years is required. • The firm has mentioned tolterodine tartrate sustained release pellets 2%. Please provide source of pellets, stability studies data of 3 batches, GMP certificate of supplier, COA of pellets and submit differential fee in case of imported pellets source. • Revise label claim as; Each prolonged-release capsule contains: Tolterodine tartrate Sustained Release Pellets Eq. to Tolterodine tartrate……...4mg" since the firm has mentioned Tolterodine tartrate sustained release pellets

		2% in master formulation. • Capsule section (General) approved vide Licensing Division letter No.F.1-12/98-Lic (Vol-II) dated 24.03.2007. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following; • **Submission of pellets source, stability study data of 03 batches, GMP certificate of pellets manufacturer and in case of imported source of pellets, applicable fee shall be submitted.** • **Revision of label claim as;** **Each prolonged-release capsule contains:** **Tolterodine tartrate sustained release pellets equivalent to Tolterodine tartrate……4mg.** • **Submission of GMP audit report from QA & LT Division, valid within last 03 years.** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
774.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	PINEX-V (5/80mg) tablet
	Composition	Each tablet contains: Amlodipine….5mg Valsartan…….80mg
	Dairy No. date of R &I fee	Dy. No 12087 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Angiotensin-II receptor blocker and Ca channel blocker
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Exforge® 5 mg/80 mg film-coated tablets (Novartis, MHRA approved)
	Me-too-status	Amlowell 5mg/80mg tablet of M/s Aspin pharma Karachi. Registration No. 100107
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Amlodipine (as besylate) ……...5mg Valsartan……. 80mg • The firm to revise master formulation and manufacturing outlines accordingly. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved as per following label claim; **"Each film-coated tablet contains:** **Amlodipine (as besylate) …….5mg** **Valsartan…….80mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
775.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.

	Brand Name + Dosage Form and Strength	PINEX-V (5/160mg) tablet
	Composition	Each tablet contains: Amlodipine….5mg Valsartan…….160mg
	Dairy No. date of R &I fee	Dy. No 12086 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Angiotensin-II receptor blocker and Ca channel blocker
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Exforge® 5 mg/160 mg film-coated tablets (Novartis, MHRA approved)
	Me-too-status	Amlowell 5mg/160mg tablet of M/s Aspin pharma Karachi. Registration No. 100106
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Amlodipine (as besylate) ……...5mg Valsartan……. 160mg • The firm to revise master formulation and manufacturing outlines accordingly. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as; • **Each film-coated tablet contains:** **Amlodipine (as besylate) …….5mg** **Valsartan…….160mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
776.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Valart 160mg tablet
	Composition	Each tablet contains: Valsartan…….160mg
	Dairy No. date of R &I fee	Dy. No 12089 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Angiotensin-II receptor blocker
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Valsartan 40mg, 80mg, 160mg and 320 mg film-coated tablets (MHRA approved)
	Me-too-status	Converge 160mg tablet, Scotmann pharmaceuticals, Islamabad. Registration No. 077726
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Valsartan……160mg, along with revision of

		manufacturing outlines. • Finished product testing methods provided for Vimet 50/500mg tablet that is Vildagliptin and metformin HCl tablet. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as; • **Each film-coated tablet contains:** **Valsartan ……. 160mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
777.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Sitaformin 50mg/500mg tablet
	Composition	Each tablet contains: Sitagliptin Phosphate Monohydrate….50mg Metformin hydrochloride……...500mg
	Dairy No. date of R &I fee	Dy. No 12107 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Dipeptidyl Peptidase-4/DPP-4 Inhibitors and Biguanide Antidiabetic combinations
	Type of form	Form 5
	Finished product specifications	Innovator specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Janumet® 50 mg/500 mg film coated tablets (MHRA approved)
	Me-too-status	Sitanext 50/500mg film coated tablet of M/s Next Pharmaceutical products Lahore Regist. No.084472
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Sitagliptin (as phosphate monohydrate) ……...50mg Metformin hydrochloride……. 500mg • The firm to revise master formulation and manufacturing outlines accordingly. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim; • **Each film-coated tablet contains:** **Sitagliptin (as phosphate monohydrate) ….50mg** **Metformin hydrochloride……...500mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form**	

	of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Latest GMP inspection report conducted within last three years.**	
778.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Sitaformin 50mg/1000mg tablet
	Composition	Each tablet contains: Sitagliptin Phosphate Monohydrate….50mg Metformin hydrochloride……...1000mg
	Dairy No. date of R &I fee	Dy. No 12108 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Dipeptidyl Peptidase-4/DPP-4 Inhibitors and Biguanide Antidiabetic combinations
	Type of form	Form 5
	Finished product specifications	Innovator specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Janumet® 50 mg/1,000 mg film coated tablets (MHRA approved)
	Me-too-status	Sitanext 50/1000mg film coated tablet of M/s Next Pharmaceutical products Lahore Regist. No.084473
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Sitagliptin (as Phosphate monohydrate) ……...50mg Metformin hydrochloride……. 1000mg • The firm to revise master formulation and manufacturing outlines accordingly. • Mater formula given is for "Lornoxicam" • In the manufacturing outlines, the drug Tizanidine has been mentioned. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with following revised label claim; • **Each film-coated tablet contains:** **Sitagliptin (as phosphate monohydrate) ….50mg** **Metformin hydrochloride……...1000mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
779.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Vimet 50mg/500mg tablet
	Composition	Each tablet contains: Vildagliptin……50mg Metformin hydrochloride…….500mg
	Dairy No. date of R &I fee	Dy. No 12103 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	Innovator specifications

	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Galvumet 50 mg/500 mg film coated tablets, Novartis Pharmaceuticals (TGA Australia)
	Me-too-status	Viglip M 50/500mg tablet of Atco laboratories, Karachi. Registration No.084647
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Vildagliptin……50mg Metformin hydrochloride…….500mg • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with following revised label claim; • **Each film-coated tablet contains:** **Vildagliptin……50mg** **Metformin hydrochloride……...500mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
780.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Vimet 50mg/1000mg tablet
	Composition	Each tablet contains: Vildagliptin…...50mg Metformin hydrochloride……1000mg
	Dairy No. date of R &I fee	Dy. No 12102 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Galvumet 50 mg/1000 mg film coated tablets, Novartis Pharmaceuticals (TGA Australia)
	Me-too-status	Velon M 50/1000mg tablet of Genix pharma, karachi. Registration No.084692
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Vildagliptin……50mg Metformin hydrochloride…….1000mg • Applied product specifications mentioned as per USP but the product monograph does not exist in USP. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.

	Decision: Approved with innovators specifications and following revised label claim; • **Each film-coated tablet contains:** **Vildagliptin……50mg** **Metformin hydrochloride……...1000mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
781.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Amsartan 20mg/5mg tablet
	Composition	Each tablet contains: Olmesartan medoxomil…...20mg Amlodipine……5mg
	Dairy No. date of R &I fee	Dy. No 12081 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Ca^{+} ion influx inhibitor of the dihydropyridine group
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too-status	Olmedip 5mg/20mg tablet by Shrooq Pharmaceuticals, Lahore. Reg. No. 068083
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Olmesartan medoxomil…...20mg Amlodipine (as besyate) ……5mg • The firm to revise master formulation and manufacturing outlines accordingly. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovators specifications and following revised label claim; • **Each film-coated tablet contains:** **Olmesartan medoxomil…...20mg** **Amlodipine (as besyate) ……5mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
782.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Amsartan 40mg/5mg tablet
	Composition	Each tablet contains: Olmesartan medoxomil…. 40mg Amlodipine……5mg

	Dairy No. date of R &I fee	Dy. No 12083 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Ca^{+} ion influx inhibitor of the dihydropyridine group
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too-status	Onato-OM 5/40mg Tablet by Sami Pharmaceuticals Karachi. Reg. No. 085606
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Olmesartan medoxomil…...40mg Amlodipine (as besyate) ……5mg • The firm to revise master formulation and manufacturing outlines accordingly. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovators specifications and following revised label claim; • **Each film-coated tablet contains:** **Olmesartan medoxomil…...40mg** **Amlodipine (as besyate) ……5mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
783.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Amsartan 40mg/10mg tablet
	Composition	Each tablet contains: Olmesartan medoxomil…. 40mg Amlodipine……10mg
	Dairy No. date of R &I fee	Dy. No 12084 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Ca^{+} ion influx inhibitor of the dihydropyridine group
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too-status	Onato-OM 10/20mg Tablet by Sami Pharmaceuticals Karachi. Reg. No. 085597
	GMP Status	Updated GMP compliance status required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Olmesartan medoxomil…...40mg Amlodipine (as besyate) ……10mg • The firm to revise master formulation and manufacturing outlines accordingly. • Provide evidence of relevant section approval by

		Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovators specifications and following revised label claim; • **Each film-coated tablet contains:** **Olmesartan medoxomil…...40mg** **Amlodipine (as besyate) ……10mg** **Firm shall submit following before issuance of registration letter:** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** **Latest GMP inspection report conducted within last three years.**	
784.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Furox 20mg tablet
	Composition	Each tablet contains: Furosemide….20mg
	Dairy No. date of R &I fee	Dy. No 12074 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Diuretics
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA approved)
	Me-too-status	Asumide 20mg tablet by Maple Pharmaceuticals Karachi. Reg. No. 089030
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• The applied formulation is uncoated tablet while the firm has mentioned coating materials in master formulation. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Firm shall submit fee of Rs.7,500 for correction/pre-approval change in master formulation as per label claim by excluding coating materials, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
785.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Furox 40mg tablet
	Composition	Each tablet contains: Furosemide….40mg
	Dairy No. date of R &I fee	Dy. No 12075 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Diuretics
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC

	Approval status of product in Reference Regulatory Authorities	(US FDA approved)
	Me-too-status	Asumide 40mg tablet by Maple Pharmaceuticals Karachi. Reg. No. 089031
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• The applied formulation is uncoated tablet while the firm has mentioned coating materials in master formulation. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Firm shall submit fee of Rs.7,500 for correction/pre-approval change in master formulation as per label claim by excluding coating materials, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
786.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Furox 5mg/5ml
	Composition	Each suspension contains: Furosemide….5mg/ml
	Dairy No. date of R &I fee	Dy. No 12076 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Diuretics
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA approved strengths are 10mg/ml & 40mg/5ml
	Me-too-status	Could not be confirmed
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of availability of applied formulation/strength that is 5mg/5ml in reference regulatory authorities as approved by the Drug Registration Board in its 275th meeting. • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, proprietary name and manufacturer. • Master formulation and manufacturing outlines of the product is not provided. • The approved strengths (10mg/ml & 40mg/5ml) in US FDA are in the form of clear solution, while the firm has applied for suspension. • Analytical testing method and specifications of the finished drug product not provided. • In MHRA shelf life for oral solution given is 18months (unopened) and 3months (when opened). • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For revision, if any to be made, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-

		2021 & 13-07-2021.
	Decision: Deferred for following; • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submission of master formulation and manufacturing outlines for the applied product.** • **Finished product specification not provided.** • **Submission of GMP audit report from QA & LT Division, valid within 03 years.** • **Submission of evidence of required manufacturing facility / section from Licensing Division.**	
787.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No.33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Fenorate 67mg capsules
	Composition	Each capsule contains: Finofibrate…….67mg
	Dairy No. date of R &I fee	Dy. No 12104 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Antilipemics and fibric acid
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Fenofibrate 67mg capsules. Each capsule contains 67 mg of micronized fenofibrate (Teva, UK) MHRA approved
	Me-too-status	Fenoget 67mg capsules (fenofibrate micronized) of Getz Pharma, Karachi. Registration No.047197
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• The firm has claimed manufacturer specifications and official monograph not available. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required.
	Decision: Approved with innovators specifications. • **Submit fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
788.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No. 33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Fenorate 200mg capsules
	Composition	Each capsule contains: Finofibrate…….200mg
	Dairy No. date of R &I fee	Dy. No 12077 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Antilipemics and fibric acid
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Fenofibrate 200mg capsules. Each capsule contains 200 mg of micronized fenofibrate (Teva, UK) MHRA approved
	Me-too-status	Fenoget 200mg capsules (fenofibrate micronized) of Getz Pharma, Karachi. Registration No.047198
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• The firm has claimed manufacturer specifications and official monograph not available.

		• Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required.
	Decision: Approved with innovators specifications. **However, before issuance of registration letter, the firm shall;** • **Submit fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
789.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No. 33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Atenox 50mg tablet
	Composition	Each tablet contains: Atenolol…….50mg
	Dairy No. date of R &I fee	Dy. No 12111 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Beta blocker, Antihypertensive
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	TENORMIN®, AstraZeneca pharmaceuticals (US FDA approved)
	Me-too-status	Lotonol 50mg tablet of M/s Lotus Pharmaceuticals Islamabad. Registration No. 090167
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• The product is available as both uncoated and film-coated tablet. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required.
	Decision: Approved. • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
790.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No. 33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Lecetine 5mg tablet
	Composition	Each tablet contains: Levocetirizine…….5mg
	Dairy No. date of R &I fee	Dy. No 12101 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Non-sedating antihistamine
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Merlozine 5mg tablet of Medicraft pharmaceuticals, Peshawar. Registration No. 101383
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each film-coated tablet contains: Levocetirizine dihydrochloride……5mg • The reference product is film coated while in master

		formulation and manufacturing outlines, the film coating materials and process not mentioned. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as; **Each film-coated tablet contains:** **Levocetirizine dihydrochloride……5mg** • **Submit fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
791.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No. 33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Nipine 10mg capsules
	Composition	Each tablet contains: Nifedipine…….10mg
	Dairy No. date of R &I fee	Dy. No 12079 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Dihydropyridine calcium channel blocker
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too-status	ADALAT 10mg capsules of M/s Bayer. Reg.No.004162
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• Clarification is required regarding the applied dosage form, as the firm label claim is for tablet while in different sections of the dossiers, the capsule dosage form is also mentioned. • Provide evidence of availability of applied formulation in reference regulatory authorities as approved by the Drug Registration Board in its 275th meeting. • The product is available as SR hard capsules, soft gelatin capsule and modified/sustained release tablets in various Reference regulatory authorities. • Confirmation of relevant manufacturing facility/section, Me-too status and requisite fee will be determined after clarification from the firm regarding applied formulation is received. • GMP inspection conducted within last 03 years required.
	Decision: Deferred for following: • **Clarification regarding the applied dosage form, as the firm label claim is for tablet while in different sections of the dossiers, the capsule dosage form is also mentioned.** • **Submission of evidence of availability of applied formulation in reference regulatory authorities as approved by the Drug Registration Board in its 275th meeting.** • **Confirmation of relevant manufacturing facility/section, Me-too status and requisite fee will be determined after clarification from the firm regarding applied formulation is received.** • **Submission of GMP audit report from QA & LT Division, valid within 03 years.** • **Submission of evidence of required manufacturing facility / section from Licensing Division.**	
792.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No. 33, Phase-1, S.I.T.E., Super Highway, Karachi.

	Brand Name + Dosage Form and Strength	Diazide 30mg tablet
	Composition	Each tablet contains: Gliclazide…….30mg
	Dairy No. date of R &I fee	Dy. No 12098 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Anti-diabetic
	Type of form	Form 5
	Finished product specifications	Innovators specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	30mg strength are in the form of modified release tablet. Diamicron 30mg MR Tablets (Les laboratories Servier, France) (MHRA approved)
	Me-too-status	Diabetron CR 30mg tablet of M/s Ferozsons laboratories, Nowshera. Registration No.070314
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of availability of applied formulation in reference regulatory authorities as adopted by the Drug Registration Board in its 275th meeting or else revise label claim/formulation as per reference product as: Each modified-release tablet contains: Gliclazide……30mg, since the applied strength is available in modified release form. • The master formulation submitted is for conventional tablets, while the applied strength is available as modified release tablet in reference regulatory authorities. • In the master formulation firm has mentioned coating materials, while the applied composition is uncoated. • The testing method provided for conventional tablet as per BP monograph. While the firm has mentioned USP specifications for finished drug product. Official monograph for modified release tablet dosage form is not available. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • GMP inspection report conducted within last 03 years required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following; • **Submission of evidence of availability of applied formulation in reference regulatory authorities as adopted by the Drug Registration Board in its 275th meeting or else revise label claim/formulation as per reference product as:** **Each modified-release tablet contains:** **Gliclazide……30mg, along with revision of master formulation, manufacturing outlines and finished product specifications.** • **Submission of GMP audit report from QA & LT Division, valid within last 03 years.** • **Submission of evidence of required manufacturing facility / section from Licensing Division.** • **The firm shall submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
793.	Name and address of manufacture / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Scheme No. 33, Phase-1, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Vasoril 10mg tablet
	Composition	Each tablet contains: Nicorandil…….10mg

	Dairy No. date of R &I fee	Dy. No 12115 dated 06-03-2019 Rs.20,000/- dated 27-02-2019
	Pharmacological Group	Potassium channel activator
	Type of form	Form 5
	Finished product specifications	BP specifications
	Pack size and Demand Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Nicorandil 10mg & 20mg tablet (Dexel Pharma laboratories UK) MHRA approved
	Me-too-status	Nikobar 10mg tablet of Barrett Hodgson, Karachi. Registration No.089211
	GMP Status	GMP inspection conducted within last 03 years required
	Remark of the Evaluator (PEC-XVII)	• Shelf life of 18 months and 15 months mentioned in reference product. • GMP inspection conducted within last 03 years required. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad.
	Decision: Approved. Firm shall submit latets GMP inspection report conduted within last three years before issuance of registration letter.	
794.	Name and address of manufacture / Applicant	M/s Alina combine pharmaceuticals (Pvt.) Ltd. A/27, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Artex 80mg IM injection
	Composition	Each ml contains: Artemether….80mg
	Dairy No. date of R &I fee	Dy. No 11675 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No.0835046 dated: 02.03.2019
	Pharmacological Group	Anti-malarial
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per PRC policy
	Approval status of product in Reference Regulatory Authorities	Artemether solution for injection 80mg/ml WHO Approved formulation
	Me-too-status	Falcinil injection of M/s Bosch Pharmaceuticals Pvt ltd. Karachi. Registration No. 055640
	GMP Status	Routine GMP inspection conducted on 08-01-2018 with conclusion: Based on the above observations their overall GMP compliance level is rated as satisfactory.
	Remark of the Evaluator (PEC-XVII)	• 1st page of Form 5 not signed by the firm/ applicant. • Proposed route of administration mentioned as "Oral" instead of Intra muscular injection. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. ◦ Panel inspection conducted on 03-10-2019 recommends renewal of DML No. 000441Frim has mentioned manufacturer specifications, while the product official monograph is given in International pharmacopoeia. Revision of finished product specifications as per IP is required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with International pharmacopoeia specifications. **Registration Board further decide that registration letter will be issued upon submission of Signed & stamped Form 5 including relevant annexure for route of administration as "Intramuscular**	

	injection", as per innovator product along with fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and route of administration as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
795.	Name and address of manufacture / Applicant	M/s Alina combine pharmaceuticals (Pvt.) Ltd. A/27, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Domin 50mg injection (50mg/ml, 5ml)
	Composition	Each ml contains: Dobutamine (as Hydrochloride) ….50mg
	Dairy No. date of R &I fee	Dy. No 11664 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No.0843227 dated: 02.03.2019
	Pharmacological Group	Cardiovascular
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	5ml ×1's, 5ml × 5's, Price not provided
	Approval status of product in Reference Regulatory Authorities	Dobutamine 12.5 mg/ml concentrate for solution for infusion (5ml, 10ml or 20ml) & Dobutamine 5 mg/ml (250 mg in 50 ml) ampoules/vials (MHRA approved) 250 mg/20 mL or 12.5mg/ml Dobutamine (as hydrochloride) concentrated injection. (TGA approved)
	Me-too-status	Dobamine 250mg vial of Biolabs (Pvt) Ltd. Islamabad. Registration No.075192 Tobuject inj 250mg (20ml) of M/s MTI Medical (Pvt.) ltd. Lahore. Registration No. 094025 Dobutine 12.5mg/ml injection of M/s Bajwa Pharmaceuticals, Sheikhupura. Registration No. 093769
	GMP Status	Routine GMP inspection conducted on 08-01-2018 with conclusion: Based on the above observations their overall GMP compliance level is rated as satisfactory.
	Remark of the Evaluator (PEC-XVII)	• 1st page of Form 5 not signed by the applicant. • Provide evidence of approval of applied formulation (50mg/ml) in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else revise label claim/formulation as per reference product. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Panel inspection conducted on 03-10-2019 recommends renewal of DML No. 000441Frim has mentioned manufacturer specifications, while the product official monograph is given in International pharmacopoeia. Revision of finished product specifications as per IP is required. • Finished product specifications not provided. Official monograph is available. • For revision, if any to be made, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following; • **Submission of evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or else revision of label claim as per reference product.** • **Submission of signed/stamped copy of 1st page of Form-5 along with relevant annexure of drug product specifications.** • **Submission of applicable fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 for pre-approval change/correction in drug product specifications.**	

796.	Name and address of manufacture / Applicant	M/s Alina combine pharmaceuticals (Pvt.) Ltd. A/27, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Linadine 1gm injection
	Composition	Each vial contains: Cephradine USP……1gm
	Dairy No. date of R &I fee	Dy. No 11668 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No.0843231 dated: 02.03.2019
	Pharmacological Group	Antibiotic (Cephalosporin)
	Type of form	Form 5
	Finished product specifications	Not provided
	Pack size and Demand Price	1's vial, price not mentioned
	Approval status of product in Reference Regulatory Authorities	Velosef 1gm vial approved in US FDA but the status is discontinued.
	Me-too-status	Valued dry powder 1gm injection of Trigon pharmaceuticals Lahore. Registration No. 042753
	GMP Status	Routine GMP inspection conducted on 08-01-2018 with conclusion: Based on the above observations their overall GMP compliance level is rated as satisfactory.
	Remark of the Evaluator (PEC-XVII)	• 1st page of Form 5 not signed • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting as the reference product is discontinued in USFDA. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Panel inspection conducted on 03-10-2019 recommends renewal of DML No. 000441Frim has mentioned manufacturer specifications, while the product official monograph is given in International pharmacopoeia. Revision of finished product specifications as per IP is required. • Finished drug product specifications and analytical testing methods not provided. However, product official monograph available (USP).
	Decision: Approved with USP specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
797.	Name and address of manufacture / Applicant	M/s Alina combine pharmaceuticals (Pvt.) Ltd. A/27, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Albac 2gm injection
	Composition	Each vial contains: Cefoperazone U.S.P as equivalent to Cefoperazone Sodium……1gm Sulbactum U.S.P as equivalent to Sulbactum Sodium….1gm
	Dairy No. date of R &I fee	Dy. No 11678 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No.0835048 dated: 02.03.2019
	Pharmacological Group	Antibiotic (Cephalosporin)
	Type of form	Form 5
	Finished product specifications	Not provided
	Pack size and Demand Price	1's vial, price not mentioned
	Approval status of product in Reference Regulatory Authorities	Sulperazon Injection by Pfizer Co. PMDA Japan Approved

	Me-too-status	Ceone 1gm injection Zesion Pharmaceuticals, Islamabad. Registration No. 045174
	GMP Status	Routine GMP inspection conducted on 08-01-2018 with conclusion: Based on the above observations their overall GMP compliance level is rated as satisfactory.
	Remark of the Evaluator (PEC-XVII)	• 1st page of Form 5 is not signed by the firm/applicant. • The strength in fee challan mentioned is 1gm and product applied is 1gm. However, the label claim/composition given is for 2gm strength, as both Cefoperazone and Sulbactam are mentioned 1gm each. Clarification is required from the firm in this regard. The label claim for the applied product should then be revised as per reference product as: (for 1gm strength) Each vial contains: Cefoperazone (as sodium) ….500mg Sulbactum (as sodium) …….500mg • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • GMP inspection report conducted within last 03 years is required. • Finished product specifications not mentioned, however official monograph available as per JP. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with JP specifications as per following label claim: **Each vial contains:** **Cefoperazone (as sodium) ….1gm** **Sulbactum (as sodium) …….1gm.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
798.	Name and address of manufacture / Applicant	M/s Alina combine pharmaceuticals (Pvt.) Ltd. A/27, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Axime 750mg injection
	Composition	Each vial contains: Cefuroxime (as Cefuroxime sodium) ……750mg
	Dairy No. date of R &I fee	Dy. No 11674 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No.0835050 dated: 02.03.2019
	Pharmacological Group	Antibiotic (Cephalosporin)
	Type of form	Form 5
	Finished product specifications	Not provided
	Pack size and Demand Price	1's vial, price not mentioned
	Approval status of product in Reference Regulatory Authorities	Zinacef 750 mg powder for solution for injection or infusion Sandoz Pharmaceuticals (MHRA approved)
	Me-too-status	Astalexim 750mg IV injection of Astellas Pharmaceuticals, Peshawar. Registration No.079751
	GMP Status	Routine GMP inspection conducted on 08-01-2018 with conclusion: Based on the above observations their overall GMP compliance level is rated as satisfactory.
	Remark of the Evaluator (PEC-XVII)	• Form 5 is not signed by the firm/applicant. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • GMP inspection report conducted within last 03 years is required. • Finished product specifications not mentioned, however

		official monograph for the drug product is available (USP).
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
799.	Name and address of manufacture / Applicant	M/s Alina combine pharmaceuticals (Pvt.) Ltd. A/27, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Axime 1.5 gm injection
	Composition	Each vial contains: Cefuroxime (as Cefuroxime sodium) ……1.5 gm
	Dairy No. date of R &I fee	Dy. No 11672 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No.0835036 dated: 02.03.2019
	Pharmacological Group	Antibiotic (Cephalosporin)
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	1's vial, price not mentioned
	Approval status of product in Reference Regulatory Authorities	Zinacef 1.5 gm powder for solution for injection or infusion Sandoz Pharmaceuticals (MHRA approved)
	Me-too-status	Astalexim 1.5gm IV injection of Astellas Pharmaceuticals, Peshawar. Registration No.079750
	GMP Status	Routine GMP inspection conducted on 08-01-2018 with conclusion: Based on the above observations their overall GMP compliance level is rated as satisfactory.
	Remark of the Evaluator (PEC-XVII)	• Form 5 is not signed by the firm/applicant. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • GMP inspection report conducted within last 03 years is required. • Finished product specifications not mentioned, however official monograph for the drug product is available (USP). • In master formulation, the quantity of Cefuroxime (as cefuroxime Na) mentioned is 1gm. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
800.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Levtam 250mg tablet
	Composition	Each film coated tablet contains: Levetiracetam ..…250mg
	Dairy No. date of R &I fee	Dy. No 12548 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841511 dated: 06.03.2019
	Pharmacological Group	Anti-seizure (antiepileptic) drug
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	1 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Levepil 250mg tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 087690
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the

		observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • GMP inspection report dated 28-12-2021 recommends renewal of DML. • Primary packaging material for applied formulation is not mentioned. • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
801.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Levtam 500mg tablet
	Composition	Each film coated tablet contains: Levetiracetam .....…500mg
	Dairy No. date of R &I fee	Dy. No 12549 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841512 dated: 06.03.2019
	Pharmacological Group	Anti-seizure (antiepileptic) drug
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	1 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Levepil 500mg tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 087691
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Primary packaging material for applied formulation is not mentioned. • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
802.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Levtam 750mg tablet

	Composition	Each film coated tablet contains: Levetiracetam 750mg
	Dairy No. date of R &I fee	Dy. No 12550 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841513 dated: 06.03.2019
	Pharmacological Group	Anti-seizure (antiepileptic) drug
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	1 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Levepil 750mg tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 087692
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Primary packaging material for applied formulation is not mentioned. • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
803.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Levtam 1000mg tablet
	Composition	Each film coated tablet contains: Levetiracetam 1000mg
	Dairy No. date of R &I fee	Dy. No 12551 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841514 dated: 06.03.2019
	Pharmacological Group	Anti-seizure (antiepileptic) drug
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	1 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Levepil 1000mg tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 087693
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Primary packaging material for applied formulation is not

		mentioned. • In the master formula, the quantity per tablet comes out to be 100mg/tablet while the applied strength is 1000mg/tablet. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.**	
804.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Ambrig 40 mg tablet
	Composition	Each film coated tablet contains: Febuxostat 40mg
	Dairy No. date of R &I fee	Dy. No 12554 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841517 dated: 06.03.2019
	Pharmacological Group	Xanthine oxidase inhibitor used for treatment of gout
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	2 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 40 mg and 80 mg tablet (Takeda), US FDA approved with following boxed warning in revised label (02-2019) WARNING: CARDIOVASCULAR DEATH Gout patients with established cardiovascular (CV) disease treated with ULORIC had a higher rate of CV death compared to those treated with allopurinol in a CV outcomes study. Consider the risks and benefits of ULORIC when deciding to prescribe or continue patients on ULORIC. ULORIC should only be used in patients who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable
	Me-too-status	Uristat 40mg tablet of M/s Medizan laboratories, Islamabad. Registration No. 087742
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • The firm has claimed manufacturer specifications, while product official monograph is not available. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovators specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
805.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.

	Brand Name + Dosage Form and Strength	Ambrig 80 mg tablet
	Composition	Each film coated tablet contains: Febuxostat .....…80mg
	Dairy No. date of R &I fee	Dy. No 12555 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841518 dated: 06.03.2019
	Pharmacological Group	Xanthine oxidase inhibitor used for treatment of gout
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	2 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 40 mg and 80 mg tablet (Takeda), US FDA approved with following boxed warning in revised label (02-2019) WARNING: CARDIOVASCULAR DEATH Gout patients with established cardiovascular (CV) disease treated with ULORIC had a higher rate of CV death compared to those treated with allopurinol in a CV outcomes study. Consider the risks and benefits of ULORIC when deciding to prescribe or continue patients on ULORIC. ULORIC should only be used in patients who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable
	Me-too-status	Uristat 80mg tablet of M/s Medizan laboratories, Islamabad. Registration No. 087743
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • The firm has claimed manufacturer specifications, while product official monograph is not available. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovators specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
806.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Dexflam 200 mg tablet
	Composition	Each film coated tablet contains: Dexibuprofen.....…200mg
	Dairy No. date of R &I fee	Dy. No 12552 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841515 dated: 06.03.2019
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	3 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Vanit 200mg tablet of M/s Getz pharma, Karachi. Registration No. 061485

	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • The raw material testing method is provided for azithromycin instead of Dexibuprofen. • The firm has claimed manufacturer specifications, while official monograph of the drug product is not available. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovators specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
807.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Dexflam 300 mg tablet
	Composition	Each film coated tablet contains: Dexibuprofen.....300 mg
	Dairy No. date of R &I fee	Dy. No 12553 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841516 dated: 06.03.2019
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	3 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Vanit 300mg tablet of M/s Getz pharma, Karachi. Registration No. 061486
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • GMP inspection report conducted within last 03 years is required. • The firm has claimed manufacturer specifications, while official monograph of the drug product is not available. • Raw material testing method is provided for azithromycin instead of Dexibuprofen, • In the master formula, Dexflam 600mg tablet is mentioned, instead of Dexflam 300mg tablet. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovators specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	

808.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	G-Taz 1mg tablet
	Composition	Each tablet contains: Glimepiride.....1mg
	Dairy No. date of R &I fee	Dy. No 12545 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841508 dated: 06.03.2019
	Pharmacological Group	Sulfonylureas
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	2 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Ajglip 1mg tablet of M/s AJM pharma, Karachi. Registration No. 100364
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • pThe firm has claimed manufacturer specifications. However, official monograph available (BP, USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
809.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	G-Taz 3mg tablet
	Composition	Each tablet contains: Glimepiride.....3mg
	Dairy No. date of R &I fee	Dy. No 12546 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841509 dated: 06.03.2019
	Pharmacological Group	Sulfonylureas
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	2 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Zoryl 3mg tablet of M/s Innvotek pharmaceuticals, Islamabad. Registration No. 099263
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • The firm has claimed manufacturer specifications.

		However, official monograph available (BP, USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
810.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	G-Taz 4mg tablet
	Composition	Each tablet contains: Glimepiride.....4mg
	Dairy No. date of R &I fee	Dy. No 12547 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841510 dated: 06.03.2019
	Pharmacological Group	Sulfonylureas
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	2 × 10, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Zoryl 4mg tablet of M/s Innvotek pharmaceuticals, Islamabad. Registration No. 099264
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • The firm has claimed manufacturer specifications. However, official monograph available (BP, USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
811.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Mukast 5mg tablet
	Composition	Each chewable tablet contains: Montelukast as sodium.....5mg
	Dairy No. date of R &I fee	Dy. No 12559 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841522 dated: 06.03.2019
	Pharmacological Group	Leukotriene receptor blocker
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	1 × 14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair (4mg, 5 mg) Chewable Tablet (US FDA Approved)
	Me-too-status	Blumont 5mg tablet of M/s Bloom pharmaceuticals, Hattar. Registration No. 102771
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia

		Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • The firm has claimed manufacturer specifications. However, official monograph available (BP, USP, JP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
812.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Suva (Rosuvastatin) 20mg tablet
	Composition	Each film coated tablet contains: Atorvastatin as calcium trihydrate.....…40mg
	Dairy No. date of R &I fee	Dy. No 12560 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841523 dated: 06.03.2019
	Pharmacological Group	Statins, HMG-CoA reductase inhibitor
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	1 × 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Rovista 20mg tablet of M/s Getz pharma, Karachi Registration No. 044045
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Composition/label claim of the product is mentioned as "Each film coated tablet contains: Atorvastatin as calcium trihydrate….40mg", while the dossier submitted is for Rosuvastatin 20mg tablet. • Master formulation and manufacturing outlines of the product not provided. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following; • **Clarification regarding applied formulation/drug product is required since the application submitted is of Suva (Rosuvastatin) 20mg tablet, while the label claim provided as:** **Each film-coated tablet contains;** **Atorvastatin (as calcium trihydrate) …….40mg.** • **Submission of master formulation and manufacturing outlines for the applied product.** • **Submission of GMP audit report by QA & LT Division, valid within last 03 years.** • **Submission of evidence of required manufacturing facility / section from Licensing Division.** • **Firm shall submit the applicable fee for correction/pre-approval change in composition, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
813.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.

	Brand Name + Dosage Form and Strength	Lipam 40mg tablet
	Composition	Each film coated tablet contains: Atorvastatin as calcium trihydrate.....…40mg
	Dairy No. date of R &I fee	Dy. No 12556 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841519 dated: 06.03.2019
	Pharmacological Group	Lipid lowering agent, HMG-CoA reductase inhibitor
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	1 × 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Truva 40mg tablet of M/s Sami pharmaceuticals, Karachi Registration No. 100511
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad.
	Decision: Approved.	
814.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Ambozial D 5mg tablet
	Composition	Each film coated tablet contains: Desloratadine.…5mg
	Dairy No. date of R &I fee	Dy. No 12558 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841521 dated: 06.03.2019
	Pharmacological Group	antihistamine
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	1 × 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (both as film coated and uncoated tablet)
	Me-too-status	Rodelo 5mg tablet of M/s Sigma pharma, Karachi Registration No. 095134
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad.
	Decision: Approved.	
815.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Dinaar 40mg capsule
	Composition	Each capsule contains: Enteric coated pellets of omeprazole equivalent to

		omeprazole…...40 mg
	Dairy No. date of R &I fee	Dy. No 12562 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841525 dated: 06.03.2019
	Pharmacological Group	Proton pump inhibitor
	Type of form	Form 5
	Finished product specifications	USP specifications
	Pack size and Demand Price	2 × 7's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too-status	Saimep 40mg capsules of M/s Saibins pharmaceuticals Islamabad. Registration No. 075437
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide source of pellets, COA, real time and accelerated stability study data of 03 batches and GMP certificate of pellets source/supplier. • Differential fee, in case of imported pellets source.
	Decision: Deferred for following; • **Submission of source of pellets, CoA of pellets, real time and accelerated stability study data of 03 batches of pellets and GMP certificate of pellets source/Manufacturer. In case of imported pellets source applicable fee shall also be submitted.** • **Submission of GMP audit report by QA & LT Division, valid within last 03 years.** • **Submission of evidence of required manufacturing facility / section from Licensing Division.**	
816.	Name and address of manufacture / Applicant	M/s Ambrosia Pharmaceuticals. Plot No. 18, Street No. 09, National Industrial Zone, Rawat-Islamabad.
	Brand Name + Dosage Form and Strength	Albizole H cream
	Composition	Each gram contains: Clotrimazole….10mg Hydrocortisone acetate….11.2mg
	Dairy No. date of R &I fee	Dy. No 12557 dated 06-03-2019 Rs.20,000/- dated 06-03-2019 Challan No.0841520 dated: 06.03.2019
	Pharmacological Group	Clotrimazole (imidazoles, antifungal, antibacterial) and Hydrocortisone acetate (mild steroid, anti-inflammatory)
	Type of form	Form 5
	Finished product specifications	BP specifications
	Pack size and Demand Price	15gm, 20gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Canesten HC cream (MHRA approved)
	Me-too-status	Conic-H cream 1% of M/s Rotex pharma Islamabad. Registration No. 100798
	GMP Status	Date: 08-10-2018 Recommendations: During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection.
	Remark of the Evaluator (PEC-XVII)	• Evidence of section approval is required. • Revise the label claim as per reference product as:

		Each gram of cream contains: Clotrimazole……...10mg Hydrocortisone (as acetate) ……...10mg • Provide evidence of separate dispensing facility for steroids materials. • The finished product specifications are mentioned as manufacturer, while the analytical testing methods provided for clotrimazole cream and Hydrocortisone cream from USP. Please clarify and revise the finished product test specifications as per pharmacopoeia as the product is mentioned in BP. • Primary packaging container not mentioned. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with BP specifications as per following label claim: **Each gram of cream contains:** **Clotrimazole……...10mg** **Hydrocortisone (as acetate) ……...10mg** • **Registration letter will be issued upon submission of evidence of availability of separate dispensing facility for steroidal materials.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

Case No. 2: Registration applications for local manufacturing of (Veterinary) drugs.
a; New cases:

1307.	Name and address of manufacture / Applicant	M/s Alina combine pharmaceuticals (Pvt.) Ltd. A/27, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	DOXIN-EF Soluble powder (Veterinary)
	Composition	Each 100gram contains: Doxycycline HCl….10 gm Tylosin Tartrate……5 gm Furaltradone HCl….15 gm Erthromycin thiocyanate…6 gm
	Dairy No. date of R &I fee	Dy. No 11681 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No.0835040 dated: 02.03.2019
	Pharmacological Group	Antibacterial and anti-infective
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	100 gm, 500 gm, 1 kg & 2.5 kg, De-controlled
	Approval status of product in Reference Regulatory Authorities	…….
	Me-too-status	Bio-Multibiotic powder of M/s Biolabs Pvt ltd. Islamabad. Registration No.043182
	GMP Status	Routine GMP inspection conducted on 08-01-2018 with conclusion: Based on the above observations their overall GMP compliance level is rated as satisfactory.
	Remark of the Evaluator (PEC-XVII)	• Cover letter and Form 5 not signed by the firm/applicant. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial.

	Decision: Deferred for review of formulation by Expert Working group.

Case No. 3: Registration applications for local manufacturing of (Human) drugs (Differential Fee cases)

a. New cases:

817.	Name and address of manufacturer/ Applicant	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi.
	Brand Name + Dosage Form + Strength	EPHANAC 50mg capsule
	Composition	Each capsule contains: Diclofenac sodium enteric coated pellets eq. to Diclofenac Sodium……50mg
	Diary No. Date of R & I & fee	Dy. No.46 dated 05-01-2011 Rs. 8,000/- dated 04-01-2011 (Photocopy), Differential fee, dated 21-07-2014, Rs. 12,000/- vide Challan No.0053249. Differential fee Rs: 80,000/- dated 02-07-2018 vide Challan No. 0756688 dated 21-06-2018 (statistical officer verified) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-rheumatics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, 30's, 100's, as per SRO
	Approval status of product in Reference Regulatory Authorities	DIFENE 50mg Capsule (Gastro-resistant) of M/s Glenwood GmbH (HPRA, Ireland approved)
	Me-too status	Mobikare 50mg Capsule of M/s Barrett Hodgson (Reg # 024699)
	GMP status	Panel inspection for renewal of DML conducted on 30-12-2021, wherein grant of renewal of DML of the firm recommended.
	Remarks of the Evaluator (PEC-XVII)	• Firm initially provided specifications as per BP monograph for prolonged release capsules. A fee of Rs: 7500/- submitted vide deposit slip No. 6442077437 for revision of specifications. • Firm has provided GMP certificate of pellets source/supplier (M/s Zen Biotech Pvt. Ltd. India) that is valid till 17-12-2022. • Firm has provided CoA of Diclofenac Sodium enteric coated pellets 30% w/w. • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2ºC and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data sheets conducted at 40 ^{0}C ± 2 ºC and 75%RH ± 5%RH of three batches for 12 months with testing points as 0, 3, 6, 9, 12, 18, 24 & 36 months (for Long term stability studies) and 0, 1, 2, 3, 6 and 12 months (for Accelerated Stability Conditions). • Capsule (General) Section available as per DML renewal inspection report dated 30-12-2021. • Official monograph for Diclofenac prolonged release capsule, gastric resistant and extended release tablets available, however, gastric resistant capsule not available.
	Decision: Approved with innovator's specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
818.	Name and address of manufacturer/ Applicant	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi.
	Brand Name + Dosage Form + Strength	EPHANAC-SR 100mg capsule
	Composition	Each capsule contains:

		Diclofenac Sodium SR pellets eq. to Diclofenac Sodium……100mg
	Diary No. Date of R & I & fee	Dy. No.44 dated 05-01-2011 Rs. 8,000/- dated 04-01-2011 (Photocopy), Differential fee dated 21-07-2014 Rs. 12,000/- vide Challan No.0053250. "Duplicate dossier, R & I verified".
	Pharmacological Group	Anti-rheumatics
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	2 × 10's, as per SRO
	Approval status of product in Reference Regulatory Authorities	Diclomax Retard Capsule 100mg (MHRA Approved)
	Me-too status	Dicloyan-S 100mg capsule Roryan Pharma, Peshawar (Reg. No. 68337)
	GMP status	Panel inspection for renewal of DML conducted on 30-12-2021, wherein grant of renewal of DML of the firm recommended
	Remarks of the Evaluator (PEC-XVII)	• Firm revised finished drug product specifications as per official monograph for Diclofenac prolonged release capsules, also further revised the assay limits as per official monograph and submitted fee Rs: 7500/- vide slip No. 57023644305 and Rs: 7500/- vide slip No.661600972, separately. • Firm has provided GMP certificate of pellets source/supplier (M/s Vision Pharmaceuticals, Islamabad) that is valid till 09-05-2022. • Firm has provided CoA of Diclofenac Sodium SR pellets 33%. • Firm has submitted real-time stability data sheets conducted at 30 0C ± 2ºC and 65%RH ± 5%RH of three batches for 48 months and accelerated stability data sheets conducted at 40 0C ± 2 ºC and 75%RH ± 5%RH of three batches for 06 months with testing points as 0, 3, 6, 9, 12, 18, 24, 36 & 48 months (for Long term stability studies) and 0, 1, 2, 3 & 6 months (for Accelerated Stability Conditions). • Capsule (General) Section available as per DML renewal inspection report dated 30-12-2021.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
819.	Name and address of manufacturer/ Applicant	Kanel Pharma, Plot No.6, Road SS-3, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	KORTEL DS tablet
	Composition	Each tablet contains: Artemether…… 40mg Lumefantrine …….240 mg
	Diary No. Date of R & I & fee	Dy. No.7053 dated 13/07/2012 Rs. 8,000/- dated 02-07-2012 (Chall No.47, Photocopy). Dy.No.574, Differential fee Rs. 12,000/- dated 26/01/2016 "Original dossier and original challans of differential fee"
	Pharmacological Group	Systemic anti-malarial agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 8's, As fixed by the MoH competent authority
	Approval status of product in Reference Regulatory Authorities	WHO prequalified drug

	Me-too status	Winterm 40mg/240mg tablet of M/s Winthrox laboratories, Karachi. Registration No. 100493
	GMP status	GMP certificate issued on 04-06-2020, based on evaluation conducted on 03-06-2020.
	Remarks of the Evaluator (PEC-XVII)	• Lumefantrine….240mg. Firm was asked to clarify and couldn't provide any clarification. The product Kortel-D DS tablet of the firm already considered in 312 Firm provided initial fee challan copy of Rs: 8000 (Challan No.47 dated 28-06-2012) for product Kortel DS tablet (Artemether…40mg & Lumefantrine….240mg), having statistical officer stampe dated 02-07-2012.Firm revised master formulation and manufacturing outlines as per label claim which is of un-coated tablet. • Firm revised finished drug product specifications as per official monograph that is International pharmacopoeia. • Tablet Section (General) mentioned in GMP certificate No. F.3-52/2020-Addl.Dir. (QA & LT-I)/93 dated 04-06-2020. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with International Pharmacopoeia specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
820.	Name and address of manufacturer/ Applicant	Roryan Pharmaceutical Industries (Pvt) Ltd. 85/B, Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Clomicit 50mg tablet
	Composition	Each tablet contains: Clomiphene Citrate ……50mg
	Diary No. Date of R & I & fee	Dy.No. 378 dated 08-06-2012, Fee Rs: 8,000/-, Date.08-06-2012 (Photo copy) Dy.No. 578 dated 27-10-2016, Differential fee: Rs. 12,000 Dated 27-10-2016, Challan No.0284427 (Photocopy) "Duplicate dossier, R & I verified".
	Pharmacological Group	Antiestrogen
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	1× 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	CLOMID® 50mg tablet (Sanofi) US FDA approved
	Me-too status	Fensipro 50mg tablet of M/s Evolution pharmaceuticals Islamabad. Registration No. 101601
	GMP status	GMP certificate No.F.11-52/2022-DRAP-71 dated 17-06-2022 issued based on evaluation conducted 13-01-2022.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised finished drug product specifications as per BP monograph for Clomifene tablets and submitted fee of Rs: 7500/- vide online deposit slip No.623150462 dated 20-07-2022. • VR & I record verified. Details incorporated in relevant column above. • Tablet Section (General) mentioned in panel inspection for renewal of DML conducted on 13-01-2022.
	Decision: Approved with BP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
821.	Name and address of manufacturer/ Applicant	Roryan Pharmaceutical Industries (Pvt) Ltd. 85/B, Hayatabad Industrial Estate, Peshawar

	Brand Name + Dosage Form + Strength	Montelu 10mg chewable tablet
	Composition	Each chewable tablet contains: Montelukast (as Montelukast Sodium) ……10mg
	Diary No. Date of R & I & fee	Dy.No. 382 dated 08-06-2012, Fee Rs: 8,000/-, Date.08-06-2012 (Photo copy) Dy.No.575 dated 27-10-2016, Differential fee: Rs. 12,000 Dated 27-10-2016, Challan No.0284433 (Photocopy)…… "Duplicate dossier, R & I verified"
	Pharmacological Group	Leukotriene receptor antagonist (antiasthmatic)
	Type of Form	Form-5
	Finished product Specification	Manufacture specification
	Pack size & Demanded Price	2× 10's, PKR 480.00/- per pack
	Approval status of product in Reference Regulatory Authorities	SINGULAIR® 10mg film coated tablets (US FDA approved with boxed warning: SERIOUS NEUROPSYCHIATRIC EVENTS See full prescribing information for complete boxed warning. Serious neuropsychiatric events have been reported in patients taking SINGULAIR. Discuss benefits and risks of SINGULAIR with patients and Caregivers. Monitor for neuropsychiatric symptoms in patients taking SINGULAIR. Discontinue SINGULAIR immediately if neuropsychiatric symptoms occur. Because the benefits of SINGULAIR may not outweigh the potential risk of neuropsychiatric symptoms in patients with allergic rhinitis, reserve use for patients who have an inadequate response or intolerance to alternative therapies.
	Me-too status	Aonukast 10mg Tablet of M/s Relizon Pharma, Lahore. Registration No. 100709
	GMP status	GMP certificate No.F.11-52/2022-DRAP-71 dated 17-06-2022 issued based on evaluation conducted 13-01-2022.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised label claim as: Each film-coated tablet contains: Montelukast (as Montelukast Sodium) ……10mg and submitted fee of Rs: 30,000/- vide online deposit slip No. 7755782079 dated 20-07-2022 and also revised master formulation and manufacturing outlines accordingly. • Firm revised the finished drug product specifications as per USP. • Tablet Section (General) mentioned in panel inspection report for renewal of DML conducted on 13-01-2022. • V R & I record verified. Details incorporated in relevant column above.
	Decision: Approved with USP specifications & revised label claim as; **Each film-coated tablet contains:** **Montelukast (as Montelukast sodium) …….10mg** **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
822.	Name and address of manufacturer/ Applicant	Roryan Pharmaceutical Industries (Pvt) Ltd. 85/B, Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Azocin 250mg capsule
	Composition	Each capsule contains: Azithromycin (as dihydrate) ……250mg
	Diary No. Date of R & I & fee	Dy.No. 375 dated 08-06-2012, Fee Rs: 8,000/-, Date.08-06-2012 (Photo copy)

		Dy.No. 576 dated 27-10-2016, Differential fee: Rs. 12,000 Dated 27-10-2016, Challan No.0284424 (Photocopy)…… "Duplicate dossier, R & I verified"
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	2× 6's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Mascin 250mg capsule of M/s Regal pharmaceuticals, Islamabad. Registration No. 099587
	GMP status	GMP certificate No.F.11-52/2022-DRAP-71 dated 17-06-2022 issued based on evaluation conducted 13-01-2022.
	Remarks of the Evaluator (PEC-XVII)	• The firm initially claimed USP specifications for their drug product. Firm was asked to provide evidence of availability of requisite testing facilities as per USP monograph, as the product testing requires Amperometric electrochemical detector. However, the firm revised the finished drug product specifications as per BP monograph and submitted fee of Rs: 7500/- vide online deposit slip No.638206400764 dated 20-07-2022. • Capsule Section (General) mentioned in panel inspection report for renewal of DML conducted on 13-01-2022. • V R & I record verified. Details incorporated in relevant column above.
	Decision: Approved with BP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
823.	Name and address of manufacturer/ Applicant	Standpharm Pakistan (Pvt) Ltd. 20Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	VEXNIL-P TABLET
	Composition	Each film-coated tablet contains: Paracetamol……325mg Tramadol Hydrochloride….37.5mg
	Diary No. Date of R & I & fee	Form-5, Dy.No. dated 23-02-2015, Differential fee: Rs. 12,000 Dated 19-02-2015 vide deposit slip No.0308737 dated 19-02-2015. "Duplicate dossier"
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	10's, MRP Rs: 10.0 per tablet
	Approval status of product in Reference Regulatory Authorities	Ultracet coated tablet (Janssen Pharma) US FDA approved. In MHRA both coated and uncoated available.
	Me-too status	Tramal plus film coated tablet of M/s The Searle Company, Lahore. Registration No. 077129
	GMP status	cGMP compliance certificate No. 101/2020-DRAP (AD-322072-1295) dated 29-06-2020 issued based on evaluation conducted on 18-02-2020.
	Remarks of the Evaluator (PEC-XVII)	• Firm was asked to submit covering letter, bearing statistical officer and DRAP R & I stamp along with fee challan copy of initial submission but did not provide the same. • Firm has revised finished drug product specifications as per USP and submitted fee Rs:7500/- vide deposit slip No.60091350.

		• Tablet Section (General) section available as per Licensing Division letter No.F.1-51/84-Lic (Vol-II) dated 30-06-2020 for renewal of Drug Manufacturing License.
	Decision: Deferred for verification of R & I record of initial submission of registration application and differential fee submission.	
824.	Name and address of manufacturer/ Applicant	Standpharm Pakistan (Pvt) Ltd. 20Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DEXIDOL SUSPENSION 100mg/5ml
	Composition	Each 5ml contains: Dexibuprofen…….100mg
	Diary No. Date of R & I & fee	Form-5, Dy.No. dated 23-02-2015, Differential fee: Rs. 12,000 Dated 19-02-2015 vide deposit slip No.0308748 dated 19-02-2015. "Duplicate dossier"
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	Rs: 60/- per 60ml, Rs: 90/- per 90ml, Rs: 101.00/- per 120ml
	Approval status of product in Reference Regulatory Authorities	International availability of applied formulation in the approved RRA could not be confirmed.
	Me-too status	Detefen liquid suspension of M/s FYNK Pharmaceuticals, Lahore. Registration No. 074443
	GMP status	cGMP compliance certificate No. 101/2020-DRAP (AD-322072-1295) dated 29-06-2020 issued based on evaluation conducted on 18-02-2020.
	Remarks of the Evaluator (PEC-XVII)	• Firm was asked to submit covering letter, bearing statistical officer and DRAP R & I stamp along with fee challan copy of initial submission but did not provide the same. • Firm was asked to provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting. However, the firm provided excerpt from PharmaGuide having various generic drug products of same formulation. • Firm provided the finished drug product specifications (Manufacture specifications). However, the firm also submitted fee Rs:7500/- vide deposit slip No.6467846931 • Liquid syrup (General) section available as per Licensing Division letter No.F.1-51/84-Lic (Vol-II) dated 30-06-2020 for renewal of Drug Manufacturing License.
	Decision: Deferred for following: • **Verification of R & I record of initial submission of registration application and differential fee submission.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
825.	Name and address of manufacturer/ Applicant	M/s. Epoch Pharmaceuticals Plot no.83-85, Sector No.15, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	EPOXCIL Dry Syrup 250mg
	Composition	Each reconstituted 5ml contains: Amoxicillin trihydrate eq. to Amoxicillin ……250mg
	Diary No. Date of R & I & fee	Dy. No. 1226 dated 19-07-2012, Rs. 8,000/- (Photocopy),

		Dy. No. 991 dated 13-05-2016 Differential fee Rs. 12,000/- vide Challan No.0138621 dated 29-04-2016 (Original), (Duplicate dossier, R & I verified)
	Pharmacological Group	Broad spectrum antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Amoxicillin 250mg Dry Suspension of Medimarker, Karachi. Registration No. 050603
	GMP status	Routine GMP inspection conducted on 26-07-2019 with conclusion as: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, M/s Epoch Pharmaceuticals is considered to be operating at SATISFACTORY level of compliance with GMP guidelines as per Drugs Act, 1976 and Drap Act 2012 and rules framed there under.
	Remarks of the Evaluator (PEC-XVII)	• Application not submitted in prescribed format. Only annexures/enclosures are provided as per check list. Firm was advised to re-submit application form as per prescribed format, but again enclosures/annexures were submitted. • Firm was advised to resubmit manufacturing outlines in elaborate manner. However, same manufacturing outlines were re-submitted. • Penicillin dry syrup section mentioned in Panel inspection for renewal of DML conducted on 10-09-2018. • Firm revised finished drug product specifications as per BP monograph for amoxicillin oral suspension. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Submission of application in prescribed Form 5, as only annexures/enclosures are provided.** • **Submission of manufacturing outlines in elaborate manner.** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for product specifications revision.**	
826.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	CLOPAM 0.5mg tablet
	Composition	Each tablet contains: Clonazepam…….0.5mg
	Diary No. Date of R & I & fee	Dy. No. 171 dated 11-01-2012, Rs. 8,000/- challan dated 06-01-2012 (Photocopy), Dy. No. 429 dated 27-01-2016 Differential fee Rs. 12,000/- vide challan No.0313818 dated 27-11-2015 (Photocopy), "Duplicate dossier, R & I verified".
	Pharmacological Group	Benzodiazepines
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	30's, 50's, As per SRO
	Approval status of product in Reference Regulatory Authorities	KLONOPIN tablet 0.5mg (USFDA approved)

	Me-too status	Catier 0.5mg tablet of M/s Medizan laboratories, Islamabad. Registration No. 102750
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (Psychotropic) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Firm has provided undertaken that the product (Clopam 0.5mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
827.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	CLOPAM 2mg tablet
	Composition	Each tablet contains: Clonazepam…….....2mg
	Diary No. Date of R & I & fee	Dy. No. 173 dated 11-01-2012, Rs. 8,000/- challan dated 06-01-2012 (Photocopy), Dy. No. 430 dated 27-01-2016 Differential fee Rs. 12,000/- vide challan No.0313816 dated 27-11-2015 (Photocopy), "Duplicate dossier, R & I verified".
	Pharmacological Group	Benzodiazepines
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	KLONOPIN tablet 2mg (USFDA approved)
	Me-too status	Catier 2mg Tablet of M/s Medizan laboratories, Islamabad. Registration No. 102751
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (Psychotropic) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • R & I record verified. Details incorporated in relevant column above.Firm has provided undertaken that the product (Clopam 2mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
828.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	CLONAP Drops 0.25% (w/v)
	Composition	Each ml contains: Clonazepam…….....2.5mg
	Diary No. Date of R & I & fee	Dy. No. 178 dated 11-01-2012, Rs. 8,000/- challan dated 06-01-2012 (Photocopy), Dy. No. 428 dated 27-01-2016 Differential fee Rs. 12,000/- vide challan No.0313817 dated 27-11-2015 (Photocopy), "Duplicate dossier, R & I verified".
	Pharmacological Group	Benzodiazepines
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications

	Pack size & Demanded Price	10ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Rivotril 2.5 mg/ml oral drops, solution (Approved by AEMPS of Spain), (AIFA Italy Approved)
	Me-too status	Clonopin Oral Solution (Drops) 2.5mg/ml of M/s Aries Pharma, Peshawar. Reg. No. 102837
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Oral liquid (Psychotropic) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • R & I record verified. Details incorporated in relevant column above.Firm has provided undertaken that the product (Clopam drops 10ml) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
829.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	TANEXA 250mg Capsule
	Composition	Each capsule contains: Tranexamic acid…….....250mg
	Diary No. Date of R & I & fee	Dy. No. 165 dated 11-01-2012, Rs. 8,000/- challan dated 20-12-2011 (Photocopy), Differential fee Rs. 12,000/- dated 27-01-2016 vide challan No.0313819 dated 12-11-2015 (Photocopy), "Duplicate dossier, R & I verified".
	Pharmacological Group	Antifibrinolytic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, 100's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Tranex 250mg capsule, AIFA Italy approved
	Me-too status	Normic 250 mg Capsules of M/s Nortech Pharmaceuticals, Islamabad. Registration No. 077973
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • R & I record verified. Details incorporated in relevant column above.Initially in the manufacturing outlines, pellets were mentioned, which are revised to powder. • Firm revised finished drug specifications as per JP monograph. • Firm has provided undertaken that the product (Tanexa 250mg capsule) has never been discussed or deferred in any meeting and that given information are true. • For above revision, firm submitted applicable fee Rs: 7500/- vide slip No. 54907592 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with JP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	

830.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	TANEXA 500mg Capsule
	Composition	Each capsule contains: Tranexamic acid…….....500mg
	Diary No. Date of R & I & fee	Dy. No. 168 dated 11-01-2012, Rs. 8,000/- challan dated 20-12-2011 (Photocopy), Differential fee Rs. 12,000/- dated 27-01-2016 vide challan No.0313820 dated 27-11-2015 (Photocopy), "Duplicate dossier, R & I verified".
	Pharmacological Group	Antifibrinolytic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Tranex 500mg capsule, AIFA Italy approved
	Me-too status	Trenfold Capsule 500mg of M/s Weatherfold, Hattar. Registration No. 103157
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • R & I record verified. Details incorporated in relevant column above. Initially in the manufacturing outlines, pellets were mentioned, which are revised to powder. • Firm revised finished drug specifications as per JP monograph. • Firm has provided undertaken that the product (Tanexa 500mg capsule) has never been discussed or deferred in any meeting and that given information are true. • For above revision, firm submitted applicable fee Rs: 7500/- vide slip No. 56887352 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with JP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
831.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	XEFLUCAN 150mg Capsule
	Composition	Each capsule contains: Fluconazole…….....150mg
	Diary No. Date of R & I & fee	Dy. No.605 dated 30-01-2012, Rs. 8,000/- challan dated 28-01-2012 (Photocopy), Dy. No. 425 dated 27-01-2016 Differential fee Rs. 12,000/- vide challan No.0540371 dated 14-12-2015 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Fluconazole 150mg capsule, MHRA approved
	Me-too status	Flucoaid Capsule 150mg of M/s Aspin Pharma, Karachi. Registration No. 103157
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.

	Remarks of the Evaluator (PEC-XVII)	• Capsule (General) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • R & I record verified. Details incorporated in relevant column above. Initially in the manufacturing outlines, pellets were mentioned, which are revised to powder. • Firm has provided undertaken that the product (Xeflucan 150mg capsule) has never been discussed or deferred in any meeting and that given information are true. • For above revision, firm submitted applicable fee Rs: 7500/- vide slip No. 68384717169 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
832.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	XEFLUCAN Dry Suspension
	Composition	Each 1ml of reconstituted suspension contains: Fluconazole……...10mg
	Diary No. Date of R & I & fee	Dy. No. 604 dated 30-01-2012, Rs. 8,000/- challan dated 28-01-2012 (Photocopy), Dy.No. 424 dated 27-01-2016 Differential fee Rs. 12,000/- vide challan No.0540372 dated 14-12-2015 (Photocopy), "Duplicate dossier, R & I verified".
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	35ml (After reconstitution), As per SRO
	Approval status of product in Reference Regulatory Authorities	Diflucan 10 mg/ml powder for oral suspension, MHRA approved
	Me-too status	Orclu Powder for Oral Suspension 10mg/ml of M/s Aulton pharma, Hattar. Registration No. 101211
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Dry Powder Suspension (General) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • R & I record verified. Details incorporated in relevant column above. Firm has provided undertaken that the product (Xeflucan dry powder suspension, 50mg/5ml) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
833.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	XELOSE Syrup
	Composition	Each 5ml contains: Lactulose…….....3.35gm
	Diary No. Date of R & I & fee	Dy. No.601 dated 30-01-2012, Rs. 8,000/- challan dated 28-01-2012 (Photocopy), Dy. No. 417 dated 27-01-2016 Differential fee Rs. 12,000/- vide challan No.0540370 dated 14-12-2015 (Photocopy) "Duplicate dossier, R & I verified".

	Pharmacological Group	Laxative
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	120ml (After reconstitution), As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	CK-Lac Syrup 3.35g/5ml of M/s CKD pharmaceuticals, Karachi. Registration No. 101105
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Oral liquid (General) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • R & I record verified. Details incorporated in relevant column. Submit differential fee as Lactulose concentrate will be imported from Fresenius Kabi Austria GmbH Estermannstraβe 17, 4020 Linz, Austria. • Provide valid cGMP certificate of Lactulose concentrate manufacturer (Imported source). • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2ºC and 65%RH ± 5%RH of three batches for 36 months, accelerated stability data sheets conducted at 40 ^{0}C ± 2 ºC and 75%RH ± 5%RH of three batches for six months and stability data sheets conducted at 25 ^{0}C ± 2ºC and 60%RH ± 5%RH of three batches for 36 months. • Clarification is required whether the Lactulose concentrate will be diluted before filling or to be filled without dilution. The manufacturing outlines and master formulation need to be revised accordingly. • Firm has provided undertaken that the product (Xelose syrup 120ml) has never been discussed or deferred in any meeting and that given information are true. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration board further decided to verify fee challan as per decision of 285th meeting of Registration Board. However, before issuance of registration letter, the firm shall: • **Submit valid GMP certificate of pellets manufactuer.** • **Submit applicable fee for pellets source approval that is Fresenius Kabi Austria GmbH Estermannstraβe 17, 4020 Linz, Austria.**	
834.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	MYOLIF 20mg tablet
	Composition	Each film-coated tablet contains: Famotidine…….20mg
	Diary No. Date of R & I & fee	Dy. No. 5913 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy. No.21667 dated 20-11-2017 Differential fee Rs. 12,000/- vide challan No.0304346 dated 15-11-2017 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	H_2-receptor antagonists.
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Pepcid Tablet (USFDA approved)
	Me-too status	Pepcidine Tablet 20mg of M/s OBS Pakistan, Karachi. Registration No. 102826
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • R & I record verified. Details incorporated in relevant column. Firm revised pharmacological group as H_2-receptor antagonists. • Firm provided the requisite list of manufacturing equipment/machinery. • Firm revise the label claim as: Each film-coated tablet contains: Famotidine…….20mg, along with revision of master formulation and manufacturing outlines. • For above revisions, the firm submitted fee of Rs:7500/- vide slip number 31071598578 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
835.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	MYOLIF 40mg tablet
	Composition	Each film-coated tablet contains: Famotidine…….40mg
	Diary No. Date of R & I & fee	Dy.No.5888 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No.21668 dated 20-11-2017 Differential fee Rs. 12,000/- vide challan No.0304347 dated 15-11-2017 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antipeptic ulcerants
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pepcid Tablet (USFDA approved)
	Me-too status	Famoxo 40mg Tablet of M/s Horizon Health Care, Lahore. Registration No. 100844
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • R & I record verified. Details incorporated in relevant column. Firm revised pharmacological group as H_2-receptor antagonists. • Firm provided the requisite list of manufacturing equipment/machinery. • Firm revise the label claim as: Each film-coated tablet contains: Famotidine…….40mg, along with revision of master formulation and manufacturing outlines. • For above revisions, the firm submitted fee of Rs:7500/- vide slip number 7945752111 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	

836.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	AVELOX 400mg tablet
	Composition	Each film-coated tablet contains: Moxifloxacin (as Hydrochloride) ….....400mg
	Diary No. Date of R & I & fee	Dy. No.5927 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy. No.21669 dated 20-11-2017 Differential fee Rs. 12,000/- vide challan No.0304344 dated 15-11-2017 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Quinolones
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Oxef 400mg Tablet of M/s Parmedic laboratories, Lahore. Registration No. 100852
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • R & I record verified. Details incorporated in relevant column. Firm revised the label claim as per reference product: Each film-coated tablet contains: Moxifloxacin (as hydrochloride) …….400mg and amended the master formulation and manufacturing outlines accordingly. • Firm revised the finished drug product specifications, as per USP. • For above revision, firm submitted applicable fee of Rs: 30,000/- vide slip No. 97840961190 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
837.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	XENID 50mg tablet
	Composition	Each film-coated tablet contains: Diclofenac Potassium….....50mg
	Diary No. Date of R & I & fee	Dy. No. 5884 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy. No.21666 dated 20-11-2017 Differential fee Rs. 12,000/- vide challan No.0304342 dated 15-11-2017 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-rheumatics
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	12.5mg, 25mg & 50mg film-coated tablets (MHRA approved)
	Me-too status	Dicloflex-P 50mg tablet of M/s MKB pharma, Peshawar. Registration No. 102825
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.

	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • R & I record verified. Details incorporated in relevant column above.Initially application submitted for Diclofenac potassium….100mg tablet. Now the firm has revised the label claim as: Each film-coated tablet contains: Diclofenac potassium……50mg but without submission of fee. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of strength from Diclofenac potassium 100mg tablet to Diclofenac potassium 50mg), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
838.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	DICLORD 100mg SR Capsule
	Composition	Each sustained release capsule contains: Diclofenac Sodium (as Diclofenac Sodium SR Pellets) ….....100mg
	Diary No. Date of R & I & fee	Dy. No. 5948 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy. No.21663 dated 20-11-2017 Differential fee Rs. 12,000/- vide challan No.0304348 dated 15-11-2017 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-inflammatory and Antirheumatic
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rhumalgan® XL 100 mg Modified Release Capsules & Difene 25mg & 50mg gastro-resistant capsules (HPRA approved)
	Me-too status	Volden Forte SR 100mg Capsule (Diclofenac sodium sustained release pellets 32% Eq to Diclofenac sodium: 100mg) of M/s Rotex Pharma, Islamabad. Registration No. 100882
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • R & I record verified. Details incorporated in relevant column above. Initially firm has not specified the pellets nature whether enteric, dual release or sustained release etc), while as per master formulation, Diclofenac sodium as enteric coated pellets are to be utilized. The firm then specified that sustained release diclofenac sodium pellets (32%) to be purchased form Vision Pharmaceuticals, Islamabad and will be re-filled. • The firm revised the label claim as: Each sustained release capsule contains: Diclofenac Sodium (as Diclofenac Sodium SR Pellets) ….....100mg • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2ºC and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data

		sheets conducted at 40 ^{0}C ± 2 ^{o}C and 75%RH ± 5%RH of three batches for six months. • CoA of Diclofenac Sodium SR pellets (32%) from Vision Pharmaceuticals, Islamabad also provided. • Official monograph available in BP. • For above revision, the firm submitted fee Rs: 30,000/- vide slip No.607703979 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with BP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
839.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	FERRY-CIN 100mg tablet
	Composition	Each tablet contains: Iron Polymaltose complex equivalent to elemental Iron…….....100mg
	Diary No. Date of R & I & fee	Dy. No. 5908 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 21665 dated 20-11-2017 Differential fee Rs. 12,000/- vide challan No.0304343 dated 15-11-2017 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-anaemic preparations
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Redroze Tablets of M/s Himont Pharma, Lahore. Registration No. 052752 Iriver 100mg Chewable Tablet of M/s Sigma Pharma International,Karachi. Registration No. 090941
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • R & I record verified. Details incorporated in relevant column above.Firm clarified that the applied formulation is in the form of chewable tablet and revised label claim as: Each Chewable tablet contains: Iron (III) Hydroxide Polymaltose complex eq. to elemental Iron……...100mg. • With regard to approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting, firm informed that since Iron preparations are not considered as drug by various reference regulatory authorities, therefore such approval is not applicable. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each Chewable tablet contains:** **Iron (III) Hydroxide Polymaltose complex eq. to elemental Iron……...100mg.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	

	• **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from plain tablet to chewable tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
840.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	LYCLEAR Lotion 5% w/v
	Composition	Each ml contains: Permethrin….50mg (5% w/v)
	Diary No. Date of R & I & fee	Dy. No.5988 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy. No.21664 dated 20-11-2017 Differential fee Rs. 12,000/- vide challan No.0304345 dated 15-11-2017 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Scabicide
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved as Permethrin Lotion 5% w/w TGA Australia approval as (QUELLADA SCABIES TREATMENT LOTION permethrin 50mg/mL bottle)
	Me-too status	Dynarix (Permethrin) 5% Lotion (Each gm contains permethrin 50mg) of M/s Dynatis Pakistan Ltd. Lahore. Registration No. 099996
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• External liquid preparation section (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) dated 27-04-2017. • V R & I record verified. Details incorporated in relevant column above.
	Decision: Deferred for submission of following docuements: • **Confirmation of required manufacturing facility / section from Licensing Division.** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for correction/pre-approval change/ in product specifications.**	
841.	Name and address of manufacturer/ Applicant	M/s Lisko Pakistan (Pvt.) Ltd. L-10/D, Block-21, Shaheed Rashid Minhas Road, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	MOXIFLOX 400mg tablet
	Composition	Each film-coated tablet contains: Moxifloxacin (as hydrochloride) …...400mg
	Diary No. Date of R & I & fee	Dy. No.997 dated 11-06-2012, Rs.8000/- Challan dated 08-06-2012, (Photocopy), Dy.No. 539 dated 13-04-2016, Differential fee Rs.12000/- dated 13-04-2016 vide Challan No.0519774 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Oxef 400mg Tablet of M/s Parmedic laboratories, Lahore. Registration No. 100852
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in the GMP certificate dated 17-08-2021.

		• V R & I record verified. Details incorporated in relevant column above.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
842.	Name and address of manufacturer/ Applicant	M/s Lisko Pakistan (Pvt.) Ltd. L-10/D, Block-21, Shaheed Rashid Minhas Road, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	DESALEX 5mg tablet
	Composition	Each film-coated tablet contains: Desloratadine …….5mg
	Diary No. Date of R & I & fee	Dy. No. 999 dated 11-06-2012, Rs.8000/- Challan dated 08-06-2012, (Photocopy), Dy.No. 541 dated 13-04-2016, Differential fee Rs.12000/- dated 13-04-2016 vide Challan No.0519776 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Deslomed Tablet 5mgof M/s Medicraft pharmaceuticals, Peshawar. Registration No. 101385
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in the GMP certificate dated 17-08-2021. • V R & I record verified. Details incorporated in relevant column above.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
843.	Name and address of manufacturer/ Applicant	M/s Lisko Pakistan (Pvt.) Ltd. L-10/D, Block-21, Shaheed Rashid Minhas Road, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	DESALEX Syrup (2.5mg/5ml)
	Composition	Each 5ml contains: Desloratadine …….2.5mg
	Diary No. Date of R & I & fee	Dy. No.998 dated 11-06-2012, Rs.8000/- Challan dated 08-06-2012, (Photocopy), Dy.No.540 dated 13-04-2016, Differential fee Rs.12000/- dated 13-04-2016 vide Challan No.0519775 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	30ml, 60ml, 120ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Desloratadine 0.5 mg/ml Oral solution (MHRA approved)
	Me-too status	Macdin 0.5mg/ml Syrup of M/s Searle IV Solutions (Pvt) Ltd. Lahore. Registration No. 101671
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator (PEC-XVII)	• Oral liquid Section (General) mentioned in the GMP certificate dated 17-08-2021. • Firm has claimed manufacturer specifications; product is non-pharmacopoeial.

		• V R & I record verified. Details incorporated in relevant column above.
	Decision: Approved with innovator's specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
844.	Name and address of manufacturer/ Applicant	M/s Atco Laboratories limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	ATCORT Ointment (0.1% w/w)
	Composition	Each gram contains: Triamcinolone Acetonide.……1mg or Triamcinolone Acetonide….0.1% w/w
	Diary No. Date of R & I & fee	Dy. No. 10 dated 17-05-2011, Rs.8000/- dated 17-05-2011, Challan (Photocopy), Dy.No. 992 dated 02-10-2015, Differential fee Rs.12000/- dated 01-10-2015 vide Challan No.0315206 (Photocopy). (Duplicate Dossier, R & I verified)
	Pharmacological Group	Anti-acne/ Dermatosis
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5gm,15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Triamcinolone acetonide 0.1% topical ointment (US FDA approved)
	Me-too status	Oralone Ointment (Each gram contains Triamcinolone acetonide…1mg) of M/s Hiranis pharmaceutical, Karachi. Registration No. 076512
	GMP status	Panel inspection for renewal of DML conducted on 22-3-2022 & 05-04-2022, wherein panel recommended the grant of renewal of DML
	Remarks of the Evaluator (PEC-XVII)	• The firm has provided copy of approved layout plan of cream/ointment manufacturing facility, mentioning three dispensing booths as: 1. Solid dispensing 1. 2. Solid dispensing 2. 3. Liquid dispensing Amongst these, firm has submitted notarized stamp paper, stating that they have dedicated solid Dispensing-1 facility for topical steroids. • Firm was advised to revise pharmacological group as "Corticosteroids, dermatological preparations". In response firm stated that there is no need of revision of pharmacological group and hence submission of any fee is not applicable. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Cream/ointment (General) Section available as per Licensing Division letter No.F.2-5/85-Lic (Vol-VI) dated 18-03-2021.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
845.	Name and address of manufacturer/ Applicant	M/s Atco Laboratories limited, B-18, S.I.T.E., Karachi.

	Brand Name + Dosage Form + Strength	ATCORT Cream (0.1% w/w)
	Composition	Each gram contains: Triamcinolone Acetonide.……1mg or Triamcinolone acetonide….0.1% w/w
	Diary No. Date of R & I & fee	Dy. No. 11 dated 17-05-2011, Rs.8000/- dated 17-05-2011, Challan (Photocopy), Dy.No. 992 dated 02-10-2015, Differential fee Rs.12000/- dated 01-10-2015 vide Challan No.0315207 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-acne/ Dermatosis
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5gm,15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Triamcinolone acetonide 0.1% topical cream (US FDA approved)
	Me-too status	K-Kort Cream (Each gram contains Triamcinolone acetonide…1mg) of Ophth-Pharma Karachi. Registration No. 067465
	GMP status	Panel inspection for renewal of DML conducted on 22-3-2022 & 05-04-2022, wherein panel recommended the grant of renewal of DML
	Remarks of the Evaluator (PEC-XVII)	• The firm has provided copy of approved layout plan of cream/ointment manufacturing facility, mentioning three dispensing booths as: 4. Solid dispensing 1. 5. Solid dispensing 2. 6. Liquid dispensing Amongst these, firm has submitted notarized stamp paper, stating that they have dedicated solid Dispensing-1 facility for topical steroids. • Firm was advised to revise pharmacological group as "Corticosteroids, dermatological preparations". In response firm stated that there is no need of revision of pharmacological group and hence submission of any fee is not applicable. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Cream/ointment (General) Section available as per Licensing Division letter No.F.2-5/85-Lic (Vol-VI) dated 18-03-2021.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
846.	Name and address of manufacturer/ Applicant	M/s Atco Laboratories limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	BETADERM-N Lotion
	Composition	Betamethasone Valerate eq. to Betamethasone… 0.1% w/v Neomycin Sulphate eq. to Neomycin …….0.35% w/v
	Diary No. Date of R & I & fee	Dy. No. 31 dated 03-05-2011, Rs.8000/- dated 03-05-2011, Challan (Photocopy), Dy.No. 992 dated 02-10-2015, Differential fee Rs.12000/- dated 01-10-2015 vide Challan No.0315208 (Photocopy). "Duplicate Dossier, R & I verified"

	Pharmacological Group	Corticosteroid combination / dermatological
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed. However, Betnovate-N cream is available in MHRA. Each 1g of cream contains 1mg (0.1% w/w) betamethasone (as valerate) and 5mg (0.5% w/w) neomycin sulfate.
	Me-too status	Betnovate-N Lotion of M/s GSK. Registration No.000252
	GMP status	Panel inspection for renewal of DML conducted on 22-3-2022 & 05-04-2022, wherein panel recommended the grant of renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Firm was asked to provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. In response firm stated that the applied formulation is not approved in any of reference regulatory authority. • Lotion (General) Section available as per Licensing Division letter No.F.2-5/85-Lic (Vol-VI) dated 18-03-2021.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
847.	Name and address of manufacturer/ Applicant	M/s Atco Laboratories limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	BETACAL GEL
	Composition	Calcipotriol Monohydrate BP eq to Calcipotriol…0.005% w/w Betamethasone Dipropionate BP eq to Betamethasone….0.05% w/w
	Diary No. Date of R & I & fee	Dy. No. 439 dated 02-11-2011, Rs.15000/- dated 02-11-2011, Challan (Photocopy), Dy.No. 992 dated 02-10-2015, Differential fee Rs.35000/- dated 01-10-2015 vide Challan No.0315205 (Photocopy). Total fee: 50,000/- "Duplicate Dossier, R & I verified"
	Pharmacological Group	Topical anti-psoriasis
	Type of Form	Form-5D
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	15gm,30gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) One gram of gel contains 50 micrograms Calcipotriol (as monohydrate) and 0.5 mg Betamethasone (as dipropionate).
	Me-too status	Could not be confirmed
	GMP status	Panel inspection for renewal of DML conducted on 22-3-2022 & 05-04-2022, wherein panel recommended the grant of renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of availability of separate dispensing facility for steroids. • Provide stability data as per decision of the DRB in 293rd meeting. • Provide the updated master formulation, method of manufacturing and drug product specifications along with stability data. • Provide the available me-too/generic drug already approved by DRAP, along with brand name, registration number and manufacturer.

		• Gel (General) Section available as per Licensing Division, DRAP Islamabad letter No.F.2-5/85-Lic (Vol-VI) dated 18-03-2021. • In response firm has stated that stability studies are in-process and will be submitted once completed.
	Decision: Deferred for following: • **Submission of stability study data as per guidelines of 293rd meeting of Drug Registration Board, along with updated/revised master formulation, method of manufacturing and drug product specifications.** • **Submission of differential fee of Rs. 25,000/- for new drug or molecule/drug not manufactured locally, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
848.	Name and address of manufacturer/ Applicant	Bryon pharmaceuticals (Pvt.) Ltd. 48-Hayatabad Industrial Estate, Peshawar.
	Brand Name + Dosage Form + Strength	VALSAR 160 tablet
	Composition	Each film coated tablet contains: - Valsartan ……...……160mg
	Diary No. Date of R & I & fee	Dy. No.86/R&I dated 03-04-2012 Rs. 8,000/- dated 03-04-2012 (Challan photocopy), Dy. No. 238/R&I dated 12-07-2016, Differential fee Rs. 12,000/- dated 12-07-2016 submitted vide deposit slip No.0556432. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-hypertensive drug
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2×7's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) DIOVAN ® (Valsartan 160mg tablets)
	Me-too status	Diovan 160mg Tablet of M/s Novartis Pharma, Karachi. Registration No. 027347
	GMP status	Panel inspection for renewal of DML and regularization of layout plan conducted on 07-09-2021 & 22-10-2021. Recommendation for renewal of DML granted and regularization of layout plan verified.
	Remarks of the Evaluator (PEC-XVII)	• Firm has revised finished drug product specifications as per official monograph (USP) without submission of fee. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet Section (General) available as per DML renewal inspection conducted on 07-09-2021 & 22-10-2021.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
849.	Name and address of manufacturer/ Applicant	Bryon pharmaceuticals (Pvt.) Ltd. 48-Hayatabad Industrial Estate, Peshawar.
	Brand Name + Dosage Form + Strength	VALSAR-H 160/12.5 tablet
	Composition	Each film coated tablet contains: - Valsartan ……...……160mg Hydrochlorothiazide.....12.5mg
	Diary No. Date of R & I & fee	Dy. No.139/R&I dated 26-04-2012 Rs. 8,000/- dated 25-04-2012 (Challan photocopy), Dy. No. 241/R&I dated 12-07-2016, Differential fee Rs. 12,000/- dated 12-07-2016 submitted vide deposit slip No.0565468. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-hypertensive drug

	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2×7's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) DIOVAN HCT® (valsartan and hydrochlorothiazide USP) tablets
	Me-too status	HC-Valdil Tablet 160/12.5 AJM pharma, Karachi. Registration No. 103056
	GMP status	Panel inspection for renewal of DML and regularization of layout plan conducted on 07-09-2021 & 22-10-2019. Recommendation for renewal of DML granted and regularization of layout plan verified.
	Remarks of the Evaluator (PEC-XVII)	• Firm has revised finished drug product specifications as per official monograph (USP) without submission of fee. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet Section (General) available as per DML renewal inspection conducted on 07-09-2021 & 22-10-2021.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
850.	Name and address of manufacturer/ Applicant	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	SPRING Tablet
	Composition	Each tablet contains: Doxylamine Succinate……10mg Pyridoxine HCl…….10mg
	Diary No. Date of R & I & fee	Dy. No. dated 08-10-2011, Rs. 8,000/- dated 08-10-2011 Challan (Photocopy), Dy. No.75-R&I dated 30-11-2015, Differential fee Rs. 12,000/- vide challan No. 0296713 dated 27-11-2015 (Photocopy), "Duplicate dossier"
	Pharmacological Group	Antihistamine and vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclegis film-coated, delayed release tablet (USFDA approved), Gastro-resistant film-coated tablet (MHRA approved)
	Me-too status	Vomifit Tablet 10/10mg of M/s Hilton Pharma, Karachi. Registration No. 097264
	GMP status	Panel inspection for renewal of DML conducted on 14-09-2020, 15-09-2020 & 21-10-2020, wherein panel recommends renewal of DML of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised label claim as per reference product as: Each delayed-release, film-coated tablet contains: Doxylamine Succinate……10mg Pyridoxine HCl…….10mg and also revised the master formulation and manufacturing outlines. The requisite fee Rs: 30,000/- submitted vide deposit slip No.224459835117. • Tablet Section (General) available as per DML inspection report dated 14-09-2020, 15-09-2020 & 21-10-2020.
	Decision: Deferred for verification of R & I record of initial submission of registration application.	

851.	Name and address of manufacturer/ Applicant	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	SPRING-S Tablet
	Composition	Each tablet contains: Doxylamine Succinate……10mg Pyridoxine HCl…….10mg Silymarin……10mg
	Diary No. Date of R & I & fee	Dy. No. dated 08-10-2011, Rs. 8,000/- dated 08-10-2011 Challan (Photocopy), Dy. No. dated 30-11-2015, Differential fee Rs. 12,000/- vide challan No. 0296714 dated 27-11-2015 (Photocopy), (Duplicate dossier)
	Pharmacological Group	Antihistamine and vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Panel inspection for renewal of DML conducted on 14-09-2020, 15-09-2020 & 21-10-2020, wherein panel recommends renewal of DML of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Provide evidence of Me-too/generic drug product already approved by DRAP, mentioning its name, registration number and manufacturer. • Tablet Section (General) available as per DML inspection report dated 14-09-2020, 15-09-2020 & 21-10-2020.
	Decision: Deferred for following: **•Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** **•Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** **• Verification of R & I record of initial submission of registration application.**	
852.	Name and address of manufacturer/ Applicant	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	VAXOL 375/20 DR tablet
	Composition	Each delayed released tablet contains: Naproxen……...375mg Esomeprazole magnesium eq. to esomeprazole…….. 20mg
	Diary No. Date of R & I & fee	Dy. No.2370 dated 08-02-2011, Rs. 15,000/- dated 08-02-2011 Challan (Photocopy), Differential fee Rs. 5,000/- dated 30-11-2015 vide challan No. 0296709 dated 27-11-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	NSAID and Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved (Vimovo delayed release tablets) 375 mg enteric-coated naproxen /20 mg immediate-release esomeprazole
	Me-too status	Could not be confirmed

	GMP status	Panel inspection for renewal of DML conducted on 14-09-2020, 15-09-2020 & 21-10-2020, wherein panel recommends renewal of DML of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each enteric film coated tablet contains: Naproxen (as enteric coated inner core) …… 375 mg Esomeprazole (As Magnesium trihydrate as film coated outer core) …….20mg • Provide stability data as per decision of the DRB in 293rd meeting. • Provide the updated master formulation, method of manufacturing and drug product specifications along with stability data. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following; • **Revision of label claim as per reference product as:** **Each enteric film coated tablet contains:** **Naproxen (as enteric coated inner core) …… 375 mg** **Esomeprazole (As Magnesium trihydrate as film coated outer core) …….20mg** • **Submission of stability study data as per guidelines of 293rd meeting of Drug Registration Board.** • **Submission of revised/updated master formulation, method of manufacturing and drug product specifications.** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
853.	Name and address of manufacturer/ Applicant	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	VAXOL 500/20 DR tablet
	Composition	Each delayed released tablet contains: Naproxen……...500mg Esomeprazole magnesium eq. to esomeprazole……... 20mg
	Diary No. Date of R & I & fee	Dy. No. 2371 dated 08-02-2011, Rs. 15,000/- dated 08-02-2011 Challan (Photocopy), Differential fee Rs. 5,000/- dated 30-11-2015 vide challan No. 0296710 dated 27-11-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	NSAID and Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved (Vimovo delayed release tablets) 500 mg enteric-coated naproxen /20 mg immediate-release esomeprazole
	Me-too status	Couldn't be confirmed
	GMP status	Panel inspection for renewal of DML conducted on 14-09-2020, 15-09-2020 & 21-10-2020, wherein panel recommends renewal of DML of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each enteric film coated tablet contains: Naproxen (as enteric coated inner core) …… 500 mg Esomeprazole (As Magnesium trihydrate as film coated outer core) …….20mg • Provide stability data as per decision of the DRB in 293rd meeting. • Provide the updated master formulation, method of manufacturing and drug product specifications along with stability data.

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following; • **Revision of label claim as per reference product as:** **Each enteric film coated tablet contains:** **Naproxen (as enteric coated inner core) …… 500 mg** **Esomeprazole (As Magnesium trihydrate as film coated outer core) …….20mg** • **Submission of stability study data as per guidelines of 293rd meeting of Drug Registration Board.** • **Submission of revised/updated master formulation, method of manufacturing and drug product specifications.** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
854.	Name and address of manufacturer/ Applicant	Vega pharmaceuticals (Pvt) Ltd. Pharma city, Plot No.4, 30-Km, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	LUMETHER tablet
	Composition	Each tablet contains: Artemether…… 80mg Lumefantrine……...480mg
	Diary No. Date of R & I & fee	Dy. No.5323 dated 28/06/2010 Rs. 8,000/- dated 24-06-2010 (Photocopy), Dy. No. dated 01-06-2016 Differential fee Rs. 12,000/- dated 31-05-2016 vide Challan No.0517705 (Photocopy) (Duplicate dossier, R & verified)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 4's, M.R.P Rs: 320/- per pack
	Approval status of product in Reference Regulatory Authorities	WHO prequalified drug (Artemether/Lumefantrine 80mg/480mg) Tablets (Novartis Pharma AG), MA108
	Me-too status	Trimed 80/480mg Tablet of M/s Trigon Pharmaceuticals (Pvt) Ltd. Lahore. Registration No. 102694
	GMP status	Panel inspection for renewal of DML conducted on 28-09-2020, 15-10-2020 & 10-11-2020, wherein panel recommends grant of renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised equipment/machinery list as coating equipment were mentioned whereas the applied formulation is in un-coated form. • Firm revised finished drug product specifications as per International pharmacopoeia. • Tablet Section (General) mentioned in DML renewal inspection conducted on 28-09-2020, 15-10-2020 & 10-11-2020. • Firm submitted fee of Rs: 7500/- vide on-line deposit slip No.34283933975 for above revision/amendments.
	Decision: Approved with International Pharmacopoeia specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
855.	Name and address of manufacturer/ Applicant	Vega pharmaceuticals (Pvt) Ltd. Pharma city, Plot No.4, 30-Km, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	DANSTRO 8mg tablet
	Composition	Each film-coated tablet contains: Ondansetron Hydrochloride eq. to Ondansetron……8mg
	Diary No. Date of R & I & fee	Dy. No.4186 dated 06/04/2011 Rs. 8,000/- dated 06-04-2011 (Photocopy), Dy. No. dated 01-06-2016 Differential fee Rs. 12,000/- dated 31-05-2016 vide Challan No.0517706 (Photocopy) (Duplicate dossier, R & I verified)
	Pharmacological Group	5-HT3-receptor antagonist with anti-emetic activity.

	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	1 × 10's, M.R.P Rs: 2000/- per pack
	Approval status of product in Reference Regulatory Authorities	ZOFRAN® (ondansetron hydrochloride) 4mg & 8mg tablets Novartis pharma (US FDA approved)
	Me-too status	Ondesmed Tablet 8mg Medicraft Pharmaceuticals (Pvt) Ltd. Peshawar. Registration No. 101379
	GMP status	Panel inspection for renewal of DML conducted on 28-09-2020, 15-10-2020 & 10-11-2020, wherein panel recommends grant of renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised label claim as per reference product Each film-coated tablet contains: Ondansetron (as hydrochloride dihydrate) ……8mg • Firm provided complete testing methods as per official monograph (BP). • Firm submitted fee of Rs: 7500/- vide on-line deposit slip No.258898379. • Firm has to submit differential fee of Rs: 22,500/- as full fee required for above revision of label claim/composition.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the differential fee of Rs. 22,500/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
856.	Name and address of manufacturer/ Applicant	Vega pharmaceuticals (Pvt) Ltd. Pharma city, Plot No.4, 30-Km, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	TRAVOTIM eye drops
	Composition	Each ml of ophthalmic solution contains: Travoprost…….40mcg Timolol (as timolol maleate) ……5mg
	Diary No. Date of R & I & fee	Dy. No.0755 dated 27-09-2010 Rs. 8,000/- dated 27-09-2010 (Photocopy), Dy. No. dated 01-06-2016 Differential fee Rs. 12,000/- dated 31-05-2016 vide Challan No.0517703 (Photocopy) (Duplicate dossier, R & I verified).
	Pharmacological Group	Anti-glaucoma + Beta blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 2.5ml, M.R.P Rs: 1000/- per vial of 2.5ml
	Approval status of product in Reference Regulatory Authorities	DuoTrav eye drops, solution (Novartis UK, MHRA approved)
	Me-too status	Co-Travost Eye Drops (Travoprost: 0.004%; Timolol maleate: 0.5%) of M/s Sante (Pvt) Ltd. Karachi. Registration No. 079950
	GMP status	Panel inspection for renewal of DML conducted on 28-09-2020, 15-10-2020 & 10-11-2020, wherein panel recommends grant of renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised finished drug product specifications as per innovators product. • Firm submitted fee of Rs: 7500/- vide on-line deposit slip No.4452987443. • Eye/Ear Drops & Nasal Spray Sections (both General & Steroid) available as per Licensing Division letter No.F.1-22/2001-Lic (Vol-II) dated 19-05-2022. • Official monograph for individual drugs available.
	Decision: Approved with innovator's specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	

857.	Name and address of manufacturer/ Applicant	Vega pharmaceuticals (Pvt) Ltd. Pharma city, Plot No.4, 30-Km, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	FLONASE nasal spray
	Composition	Each 100mg spray delivered contains: Fluticasone propionate…….50 mcg
	Diary No. Date of R & I & fee	Dy. No.6330 dated 14-07-2010 Rs. 8,000/- dated 14-07-2010 (Photocopy), Dy. No. dated 01-06-2016 Differential fee Rs. 12,000/- dated 31-05-2016 vide Challan No.0517704 (Photocopy) (Duplicate dossier R & I verified)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	Rs: 300/- per vial of 120 spray doses.
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Kartico Nasal SprayRotex Pharma (Pvt) Ltd., Islamabad. Registration No.099155
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• The various label claim mentioned for reference product as: Each 100-microliter metered spray contains 50 microgram (mcg) of fluticasone propionate" Each spray delivers 100 mg suspension containing 50 micrograms of fluticasone propionate as a delivered dose. Aqueous suspension of 0.5 mg (500 micrograms)/ml fluticasone propionate. Each actuation delivers 100 mg suspension containing 50 micrograms of fluticasone propionate as a delivered dose. • Eye/Ear Drops & Nasal Spray Sections (both General & Steroid) available as per Licensing Division letter No.F.1-22/2001-Lic (Vol-II) dated 19-05-2022.
	Decision: Deferred for clarification of label claim, since reference product has declared label claim in terms of "microliter of delivered dose contains" whereas firm has applied in terms of "mg of delivered dose contains".	
858.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	REOPOL Suspension (120mg/5ml)
	Composition	Each 5ml of syrup contains: Paracetamol……120mg
	Diary No. Date of R & I & fee	Dy. No.4485 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0001229 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antipyretic, analgesic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	60ml,120ml,450mlRs:45.50/-, Rs:84.20/-, Rs: 298.62/-
	Approval status of product in Reference Regulatory Authorities	Paracetamol 120 mg/5 ml Oral Suspension by M/s Pinewood Laboratories Limited (MHRA approved)
	Me-too status	Fempol 120mg/5ml suspension by M/s Atlantic Pharmaceuticals Pvt. Limited. (Reg# 062314)
	GMP status	Panel inspection to check the rectifications of deficiencies, conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion

		that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • Firm revised paracetamol quantity in master formula from 40mg/ml to 120mg/5ml. • In the label claim the word "Syrup" revised as "Suspension". • At annexure-VI, in the product specifications table, the assay mentioned is for Promethazine HCl with limits of 90-110%. Firm rectified and provided correct assay of paracetamol. • The finished drug product specifications given as per B.P monograph for paracetamol oral suspension. In B.P the different monographs given are: Pediatric paracetamol oral suspension 5% w/v (250mg/5ml), Paracetamol Oral Suspension and Pediatric Paracetamol Oral Solution 2.4% w/v (120ml/5ml). • Oral liquid Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of oral liquid section availability. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 5ml suspension contains:** **Paracetamol….120mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from syrup to suspension), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
859.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	PROMIZINE Elixir (5mg/5ml)
	Composition	Each 5ml of syrup contains: Promethazine HCl……5mg
	Diary No. Date of R & I & fee	Dy. No.4489 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0044192 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	First generation antihistamine, antiemetic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	120ml,450ml Rs:45.50/-
	Approval status of product in Reference Regulatory Authorities	Phenergan Elixir 5mg/5ml (MHRA approved)
	Me-too status	DEMATIC Oral Solution 5mg/5ml of M/s Oakdale pharmaceuticals, Peshawar. Registration No. 087037

	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • The dosage form mentioned in application form was oral suspension, while the formulation applied is Elixer/solution. Firm revised/rectify it and also replaced the word "syrup" in label claim as "elixir". • Oral liquid Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of oral liquid section availability. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 5ml elixir contains:** **Paracetamol….120mg** **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from suspension to elixir), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
860.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	RIOZINE syrup (5mg/5ml)
	Composition	Each 5ml syrup contains: Cetirizine Dihydrochloride……5mg
	Diary No. Date of R & I & fee	Dy. No. 4487 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs.12,000/- vide Challan No.0001236 dated 18-09-2013 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	H_1 receptor antagonist
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	60ml, Rs:36.50/-
	Approval status of product in Reference Regulatory Authorities	CHILDREN'S ZYRTEC ALLERGY (US FDA approved)
	Me-too status	Tririz 1mg Oral Solution of Trillium Pharmaceuticals Faisalabad. Registration No. 096416
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that

		they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • Firm revised label claim as: Each 5ml syrup contains: Cetirizine hydrochloride……5mg • In official monograph, the structural formula given is cetirizine dihydrochloride, but the content mentioned is cetirizine hydrochloride. • Oral liquid Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of oral liquid section availability. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 5ml syrup contains:** **Cetirizine hydrochloride……5mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
861.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	REOTRAN pediatric suspension
	Composition	Each 5ml of syrup contains: Trimethoprim……...40mg Sulphamethoxazole……...200mg
	Diary No. Date of R & I & fee	Dy. No.4486 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0001225 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibacterial-sulfonamide
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml, Rs:45/-
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Methotrix Suspension of M/s Dr. Raza pharma, Peshawar. Registration No. 098788
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required.

		• Firm replace the word "syrup" in label claim by "suspension", as the applied formulation is in suspension form. • Oral liquid Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of oral liquid section availability. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 5ml suspension contains:** **Trimethoprim……...40mg** **Sulphamethoxazole……...200mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from syrup to suspension), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
862.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	XANTAL suspension
	Composition	Each 5ml of syrup contains: Albendazole……...200mg
	Diary No. Date of R & I & fee	Dy. No.4488 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0001234 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml, Rs:28.30/-
	Approval status of product in Reference Regulatory Authorities	ZENTEL 0.4 g/10 mL, oral suspension GSK (ANSM France)
	Me-too status	Intestinil Oral Suspension of M/s Sapient Pharma, Lahore. Registration No. 077096
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Provide DRAP R & I stamped cover letter copy for differential fee submission in the year 2013. • Firm replace the form "syrup" in label claim by "suspension", as the applied formulation is in suspension form. • Oral liquid Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan

		under DML No.000156 (Formulation)", evidence of oral liquid section availability. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 5ml suspension contains:** • **Albendazole……...200mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from syrup to suspension), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
863.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	RIOFAX topical ointment
	Composition	Each 1gm of ointment contains: Polymyxin B Sulphate……...1000 IU Bacitracin Zinc……...500 IU
	Diary No. Date of R & I & fee	Dy. No. 4483 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0001233 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	20gm, Rs:66.00/-
	Approval status of product in Reference Regulatory Authorities	Health Canada approved with schedule as OTC and electronic product monograph not available. In DailyMed data base, the product is available as OTC drug (Polysporin first aid antibiotic, Double antibiotic ointment) US FDA approved but status is discontinued.
	Me-too status	Polycort Ointment of Aspin pharma, Karachi. Registration No. 091008
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • Firm revised the quantity of Bacitracin Zinc in master formulation as per label claim from 0.39kg to 0.204kg for a 30kg batch size. • Ointment Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of Semi solid (cream, ointment, gel lotion) (General) Section availability.

		• Previous approval given as per US FDA, HPRA and MHRA.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
864.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	RIOMYCIN ointment (0.5% w/w)
	Composition	Each 1gm of ointment contains: Neomycin Sulphate……1mg (0.5% w/w)
	Diary No. Date of R & I & fee	Dy. No.4480 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0044193 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Aminoglycoside Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	15gm, Rs:18.00/-
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Neomycin Skin Ointment Neomycin Sulphate….0.5% w/w (Antibacterial) Adamjee Pharmaceuticals, Karachi. Registration No. 042197 Neomycin Skin Ointment (Neomycin Sulphate 5mg) Eros Pharmaceuticals, Karachi., Karachi. Registration No. 031261
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Firm revised label claim as: Each 1gm of ointment contains: Neomycin Sulphate……5mg (0.5% w/w) • The finished drug product specifications are given as per USP monograph, while firm have referred to BP in their SOP for finished drug product specifications. Firm revised finished drug product specifications from USP to BP. • Ointment Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of Semi solid (cream, ointment, gel lotion) (General) Section availability. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.

	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of fee Rs. 30,000/- for correction/pre-approval change in composition (correction/change of formulation from 1mg per gm to 5mg per gram), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
865.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	RIODEX N Cream
	Composition	Each 1gm of ointment contains: Dexamethasone Sodium Phosphate….0.1% w/w Neomycin Sulfate……0.5% w/w
	Diary No. Date of R & I & fee	Dy. No.4482 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0001227 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Combination corticosteroid + antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	15gm, Rs:35.00/-
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Dexa-N Cream Switss Pharmaceuticals, Karachi. Registration No.020223 Dexazone-N Cream Adamjee Pharmaceuticals, Karachi. Registration No.047455 Kanadex-N Cream, DEXAMETHASONE SODIUM PHOSPHATE 1mg NEOMYCIN SULPHATE 3500IU KRKA Karachi. Registration No.012475
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • As per master formulation, the quantity of dexamethasone sodium phosphate for 30kg batch size given as 0.3kg, which does not corresponds/match with the label claim. The firm revised the master formulation with correct quantity of dexamethasone sodium phosphate that is 0.03kg. • Provide evidence of separate dispensing facilities for steroidal materials. • Ointment Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of

		Semi solid (cream, ointment, gel lotion) (General) Section availability. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of availability of separate dispensing facilities for steroidal materials.**	
866.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	RIOVATE N cream
	Composition	Each 1gm of ointment contains: Betamethasone Valerate.…0.1% w/w Neomycin Sulfate……0.5% w/w
	Diary No. Date of R & I & fee	Dy. No.4479 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0001228 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Combination corticosteroid + antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	20gm, Rs:72.00/-
	Approval status of product in Reference Regulatory Authorities	Betnovate N cream (MHRA approved)
	Me-too status	Betnovate – N Cream by GSK (Reg. # 000254).
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • Firm revise label claim as per reference product as: Each 1gm of cream contains: Betamethasone valerate eq. to Betamethasone…... ……1mg (0.1% w/w) Neomycin sulphate…….5mg (0.5% w/w) and also revised the master formulation accordingly. • Firm has claimed manufacturer specifications. Official monograph not available. • Provide evidence of separate dispensing facilities for steroidal materials. • Ointment Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of Semi solid (cream, ointment, gel lotion) (General) Section availability. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.

	Decision: Approved as per following label claim: **"Each 1gm of cream contains:** **Betamethasone valerate eq. to Betamethasone …. …… 1mg (0.1% w/w)** **Neomycin sulphate ……. 5mg (0.5% w/w)"** **Registration letter will be issued upon submission of following:** • **Evidence of availability of separate dispensing facilities for steroidal materials.** • **Submission of fee Rs: 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 as label claim revised.**	
867.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	RIOVATE ointment
	Composition	Each 1gm of ointment contains: Betamethasone (as Valerate)….1mg (0.1% w/w)
	Diary No. Date of R & I & fee	Dy. No. 4481 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0001226 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Topical corticosteroid
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	20gm, Rs:65.50/-
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Betnovate ointment of M/s GSK, Karachi. Registration No. 000257
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • The initial and differential challan submitted bearing the product name as "Riovate-N Ointment". Firm re-submit the initial challan with the word "N" cross-marked. Moreover, as per R & I record, the product applied with Dy.No.4481 dated 08-08-2009 is "Riovate-N ointment 5gm". • The firm revised master formulation by adjusting the salt factor of Betamethasone valerate. • Provide evidence of separate dispensing facilities for steroidal materials. • Ointment Section mentioned in panel inspection conducted on 07-01-2020, to check the rectifications of deficiencies. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of Semi solid (cream, ointment, gel lotion) (General) Section availability.

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration letter will be issued upon submission of following: • **Evidence of availability of separate dispensing facilities for steroidal materials.** • **Clarification is required since the initial and differential fee challans copies provided bearing product name as "Riovate-N Ointment", while the product applied/mentioned in duplicate application (Form-5) is Riovate ointment.** • **Submission of fee Rs: 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 as label claim revised.**	
868.	Name and address of manufacturer/ Applicant	M/s Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore.
	Brand Name + Dosage Form + Strength	VOLTREX gel
	Composition	Each 100gm of gel contains: Diclofenac Diethyl Ammonium Salt 1.16gm equivalent to Diclofenac Sodium….1gm
	Diary No. Date of R & I & fee	Dy. No. 4484 dated 08-08-2009, Rs. 8,000/- dated 08-08-2009 (Photocopy), Dy. No. dated Differential fee Rs. 12,000/- vide Challan No.0001230 dated 18-09-2013 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Other dermatological/ topical NSAID
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	20gm, Rs:128.60/-
	Approval status of product in Reference Regulatory Authorities	Voltarol 1.16% Emulgel, gel, 1g of Voltarol Emulgel contains 11.6mg of the active substance diclofenac diethylammonium, which corresponds to 10mg diclofenac sodium. (MHRA approved)
	Me-too status	Dicmaf 1% gel of M/s Mafins Pharma, Karachi. Registration No. 079899
	GMP status	Panel inspection to check the rectifications of deficiencies conducted on 07-01-2020 and concluded that "In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• R & I cover letter of differential fee submission in the year 2013 is required. • Firm has provided letter No.F.1-24/93-Lic (Vol-II) dated 03-11-2021 titled as "approval of revised layout plan under DML No.000156 (Formulation)", evidence of Semi solid (cream, ointment, gel lotion) (General) Section availability.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
869.	Name and address of manufacturer/ Applicant	M/s Lowitt Pharma (Pvt.) Ltd. Plot No.24-Industrial Estate, Hayatabad, Peshawar
	Brand Name + Dosage Form + Strength	NURZOL 40mg capsule
	Composition	Each capsule contains: Omeprazole……40mg
	Diary No. Date of R & I & fee	Dy. No. 15 dated 15-02-2011, Rs. 8,000/- challan dated 31-01-2011 (Photocopy, no statistical officer stamp mentioned),

		Rs: 7000/- dated 04-01-2013 (Challan No. 82 dated 26-12-2012, Photocopy), Dy. No. dated 08-08-2017 Rs: 5000/- 01-08-2017 vide challan No. 0588736 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antipeptic ulcerants
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	Parkoprazole Capsule 40mg of M/s Parkar Pharma, Kotri. Registration No. 102818
	GMP status	Panel inspection report dated 01-08-2019 for grant of cGMP certificate provided, wherein panel recommended for award of cGMP certificate to the firm.
	Remarks of the Evaluator (PEC-XVII)	• Cover letter bearing only statistical officer stamp for Rs: 7000/- dated 04-01-2013 (initial submission) provided. While two fee challan of Rs: 8000/- dated 31-01-2011 and fee challan Rs: 7000/- bearing statistical officer stamp dated 04-01-2013 are also provided. Differential fee Rs: 5000/- submitted on 08-08-2017. • Signed Form 5 re-submitted by the firm. • Firm revised label claim as: Each delayed-release capsule contains: Omeprazole ……40mg (As enteric coated pellets) and submitted fee Rs: 30,000/- vide online deposit slip No.30575305912. • Firm has changed pellets source/supplier from Pharma Gen Limited, Lahore (specified in differential fee submission cover letter submitted in 2017) to Vision Pharmaceuticals, Islamabad. • Firm has submitted CoA of omeprazole pellets 8.5%, DML of pellets supplier and GMP certificate with validity till 09-05-2022. • Firm has also submitted real-time stability data sheets conducted at 30 ºC ± 2ºC and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data sheets conducted at 40 ºC ± 2 ºC and 75%RH ± 5%RH of three batches for six months. • Firm has revised master formulation by excluding 5% overage. • Verification of initial and differential fee submission required. • Confirmation of fee for pellets source change required. • Capsule Section (General) approved/available as per Licensing Division letter No.F.3-3/2002-Lic (Vol-I) dated 11-05-2022.
	Decision: Approved with revised label claim as: **Each delayed-release capsule contains:** **Omeprazole ……40mg** **(As enteric coated pellets)** • **Registration board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
870.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	KLARACIN 250mg tablet
	Composition	Each film-coated tablet contains:

		Clarithromycin…….250mg
	Diary No. Date of R & I & fee	Dy. No. 172 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548608 dated 20-10-2015 (Photocopy), (Duplicate dossier, R & I verified"
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Clareta 250mg tablet of M/s Arreta pharmaceuticals, Rawalpindi. Registration No.100669
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section available as per Licensing Division letter No.F.2-25/84-Lic (Vol-I) dated 22-11-2021. • Firm revised finished drug product specifications as per official monograph (USP). • Firm has submitted fee of Rs: 7500/-vide online deposit slip No.61549370 for above revision.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
871.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	KLARACIN 500mg tablet
	Composition	Each film-coated tablet contains: Clarithromycin…….500mg
	Diary No. Date of R & I & fee	Dy. No.171 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548609 dated 20-10-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Clareta 500mg tablet of M/s Arreta pharmaceuticals, Rawalpindi. Registration No.100659
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section available as per Licensing Division letter No.F.2-25/84-Lic (Vol-I) dated 22-11-2021. • Firm revised finished drug product specifications as per official monograph (USP).

		• Firm has submitted fee of Rs: 7500/-vide online deposit slip No.66824730752 for above revision.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
872.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	MOXICIN 400mg tablet
	Composition	Each film-coated tablet contains: Moxifloxacin (as hydrochloride) …….400mg
	Diary No. Date of R & I & fee	Dy. No. 174 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548614 dated 20-10-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Oxef 400mg Tablet of M/s Parmedic laboratories, Lahore. Registration No. 100852
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section available as per Licensing Division letter No.F.2-25/84-Lic (Vol-I) dated 22-11-2021. • Firm revised label claim as per reference product as Each film-coated tablet contains: Moxifloxacin (as hydrochloride) …….400mg. The firm had given label claim as "Moxifloxacin". • The firm has revised finished drug product specifications as per official monograph (USP). • Firm has submitted fee of Rs: 7500/-vide online deposit slip No.80308671 for above revision. • The firm has to submit differential fee of Rs: 22,500/- for revision of label claim.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
873.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	PEP-EEZ 40mg tablet
	Composition	Esomeprazole…….40mg
	Diary No. Date of R & I & fee	Dy. No. 175 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548615 dated 20-10-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5

	Finished product Specification	Not provided
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Esomeprazole 40mg Gastro-resistant Tablets)
	Me-too status	Esbril 40mg tablet (Esomeprazole as magnesium tri-hydrate 40mg) of M/s Briell Pharmaceuticals (Pvt) Ltd. Lahore, Lahore Registration No. 103263
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section available as per Licensing Division letter No.F.2-25/84-Lic (Vol-I) dated 22-11-2021. • Firm provided/revised label claim as per reference product as Each gastro-resistant tablet contains: Esomeprazole (as Magnesium trihydrate) …….40mg and revised master formula and manufacturing outlines accordingly. • Official monograph not available and firm has claimed manufacture specifications. • Firm has submitted fee of Rs: 7500/-vide online deposit slip No.36514367761 for above revision. • The firm has to submit differential fee of Rs: 22500/- for revision of label claim.
	Decision: Approved with innovator's specifications and revised label claim as: **Each gastro-resistant tablet contains:** **Esomeprazole (as Magnesium trihydrate) …….40mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
874.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	ZINC SULPHATE 20mg tablet
	Composition	Zinc sulphate….
	Diary No. Date of R & I & fee	Dy. No. 167 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548611 dated 20-10-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Zinc supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified Zincfant dispersible tablet 20 mg manufactured by Laboratories Pharmaceutique s Rodael –France
	Me-too status	Zixol 20mg dispersible tablet of M/s Vision pharmaceuticals, Islamabad. Registration No. 099565
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.

	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section available as per Licensing Division letter No.F.2-25/84-Lic (Vol-I) dated 22-11-2021. • Firm provided/revised label claim as per reference product as: Each dispersible tablet contains: Zinc sulphate monohydrate eq to elemental zinc……. 20mg and revised manufacturing outlines accordingly. • Official monograph available in International Pharmacopoeia as Paediatric Zinc Sulphate tablet (dispersible) and in USP, BP as Zinc Sulphate tablet. • Firm revised finished drug product specifications as per official monograph (USP). • Firm has submitted fee of Rs: 7500/-vide online deposit slip No.68740995378 for above revision. • The firm has to submit differential fee of Rs: 22500/- for revision of label claim.
	Decision: Approved with USP specifications and revised label claim as: **Each dispersible tablet contains:** **Zinc sulphate monohydrate eq to elemental zinc……. 20mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
875.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	ZINC SULPHATE Syrup
	Composition	Zinc sulphate….
	Diary No. Date of R & I & fee	Dy. No. 168 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548610 dated 20-10-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Zinc supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Applied formulation has been verified from International Pharmacopoeia of WHO Available in IP as solution (Available strengths: 10 mg or 20 mg of zinc per 5 mL)
	Me-too status	Zevro Syrup 10mg/5ml Reg. No. 77058 Zincasa DS 20mg/5ml Syrup of M/s Macter Int (R#076710)
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Liquid (General) Section available as per Licensing Division letter No.F.2-25/84-Lic (Vol-I) dated 22-11-2021. • Initially, the product strength, composition/master formulation and label claim had not been mentioned but firm provided the strength and label claim as per reference product as: Each 5ml Contains:

		Elemental Zinc (as Zinc Sulphate Monohydrate) ……20mg • Firm revised finished drug product specifications as per official monograph (USP). • Official monograph available in International Pharmacopoeia as Paediatric Zinc Sulphate oral solution and in USP as Zinc Sulphate oral solution. • Firm has submitted fee of Rs: 7500/-vide online deposit slip No.0794815858 for above revision. • The firm has to submit differential fee of Rs: 22500/- for revision of label claim.
	Decision: Approved with USP specifications and revised label claim as: **Each 5ml Contains:** **Elemental Zinc (as Zinc Sulphate Monohydrate) ……20mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
876.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	EXIDOL DROPS (80mg/0.8ml)
	Composition	Each ml contains: Paracetamol……...100mg
	Diary No. Date of R & I & fee	Dy. No. 169 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548612 dated 20-10-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Analgesic & antipyretic, Anilide
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	15ml, 30ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	ZAPAIN 500MG/5ML ORAL SOLUTION (MHRA approved) (the product is qualitatively and quantitatively the same as Paracetamol Infant Drops 100 mg/ml, Infadrops (PL 12762/0135), differing only in pack size
	Me-too status	Children's Panadol Drops of M/s GSK OTC (Pvt) Ltd.Jamshoro. Registration No. 101140
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Liquid (General) Section available as per Licensing Division letter No.F.2-25/84-Lic (Vol-I) dated 22-11-2021. • Firm revised manufacturing outlines according to the applied formulation. • Firm provided/specified label claim as per reference product as Each ml Contains: Paracetamol…...100mg • Official monograph for the strength 100mg/ml is not available. • Firm has submitted fee of Rs: 7500/-vide online deposit slip No.10848172 for above revision.

	Decision: Approved with USP specifications. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
877.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	EXIDOL PLUS SYRUP (250mg/5ml)
	Composition	Paracetamol….
	Diary No. Date of R & I & fee	Dy. No. 170 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548613 dated 20-10-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Analgesic & antipyretic, Anilide
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Paracetamol 250mg/5ml Oral Suspension (MHRA approved)
	Me-too status	Bemol 6 Plus Suspension of M/s BJ Pharmaceuticals, Lahore. Registration No. 102595
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Liquid (General) Section available as per Licensing Division letter No.F.2-25/84-Lic (Vol-I) dated 22-11-2021. • Firm revised manufacturing outlines according to the applied formulation. • Firm provided master formulation of the applied product. • The reference product is in suspension form while the firm has applied for syrup form. • Firm provided/specified label claim as: Each 5 ml suspension contains: Paracetamol…...250mg • Firm has submitted fee of Rs: 7500/-vide online deposit slip No.8080748342 for above revision.
	Decision: Approved with USP specifications and revised label claim as: **Each 5ml suspension contains:** **Paracetamol ……250mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
878.	Name and address of manufacturer/ Applicant	M/s Karachi Chemical Industries (Pvt.) Ltd. Plot No. F/25, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	KLARACIN SYRUP (125mg/5ml)
	Composition	Clarithromycin……
	Diary No. Date of R & I & fee	Dy. No. 173 dated 28-02-2011, Rs. 8,000/- dated 28-02-2011 Challan (Photocopy) Dy. No. 692 dated 27-10-2015 Differential fee Rs. 12,000/- vide challan No.0548607 dated 20-10-2015 (Photocopy),

		"Duplicate dossier, R & I verified"
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Granules for oral suspension)
	Me-too status	Texklar 125mg/5ml Dry Suspension of Rotex pharma Islamabad. Registration No. 097435
	GMP status	Panel inspection for renewal of DML and regularization of approved layout plan conducted on 12-10-2021, wherein the panel recommends the grant of renewal of DML and regularization of approved layout plan of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of relevant section by Licensing Division, DRAP Islamabad. • As per master formulation, the formulation is in syrup form. Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else provide label claim/composition as per reference product as: Each 5ml of the reconstituted suspension contains: Clarithromycin…….125mg and revise master formulation and manufacturing outlines accordingly. • The formulation provided is not as per reference product, which is in the form taste-masked granules. Please clarify as to how the applied formulation is in line with reference product or else specify source of taste masked pellets, provide CoA of pellets along with stability data of 03 batches of such pellets. In case of imported pellets, submit the differential fee as well. • Provide finished drug product specifications. • Firm has submitted fee of Rs: 7500/-vide online deposit slip No.8080748342 for finished drug product specifications.
	Decision: Deferred for following: • **Revision of label claim as per reference product as:** **Each 5ml of the reconstituted suspension contains:** **Clarithromycin…….125mg** **(as taste mask granules)** • **Submission of pellets source, CoA of pellets, stability study data of 03 batches of pellet and GMP certificate of pellets manufacturer. In case of imported pellets source, applicable fee should also be submitted.** • **Firm shall submit the fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of formulation from syrup to suspension), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Confirmation of required manufacturing facility / section from Licensing Division.**	
879.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	MIKACIN 500MG INJECTION (250mg/ml)
	Composition	Each ml contains: Amikacin Sulphate…...250mg
	Diary No. Date of R & I & fee	Dy. No.2254 dated 16-06-2011, Rs. 8,000/- dated 16-06-2011 Challan (Photocopy) Dy. No. 266 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0540358 dated 10-12-2015 (Photocopy),

		(Duplicate dossier, R & I record of initial submission verified vide letter No.F.1-11/2019-Reg-II dated 07-05-2020. Verification of initial and differential fee challans required)
	Pharmacological Group	Aminoglycoside antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1× 2ml ampoule, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Amikacin 250mg/ml Injection) 1ml of solution for injection contains 250mg of amikacin (as sulphate). 1 vial of 2ml of solution for injection contains 500mg of amikacin (as sulphate).
	Me-too status	AMC 500mg/2ml Injection of M/s Rotex pharma, Islamabad. Registration No. 099160
	GMP status	Inspection for ground check/inspection of NOC for quota allocation of controlled substances conducted on 17-02-2022 submitted as evidence of GMP status of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Liquid Injectable (General ampoules only) section approved vide Licensing Division letter No.F.1-38/91-Lic (Vol-I) dated 10-08-2015. • Firm revised label claim as per reference product as: Each 2ml ampoule contains: Amikacin (as sulphate) …...500mg • Firm revised the manufacturing process/flow chart as initially the manufacturing process/flow chart submitted depicts sterile powder filing in vials, while the formulation applied is solution for injection. • Firm resubmit the HVAC and air handling system parameters for injection section as initially these were provided for tablet and capsule sections. • No fee submitted for above mentioned revision/amendments. Firm stated that the applied product is a generic product having same formulation as innovator/reference product, so no need to pay further fee.
	Decision: Approved with revised label claim as: **Each 2ml ampoule contains:** **Amikacin (as sulphate) …...500mg.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the differential fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
880.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	CECAM INJECTION (Piroxicam 20mg/ml)
	Composition	Each ml contains: Piroxicam…...20mg
	Diary No. Date of R & I & fee	Dy. No. 2270 dated 16-06-2011, Rs. 8,000/- dated 16-06-2011 Challan (Photocopy) Dy. No. 267 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0540349 dated 10-12-2015 (Photocopy), (Duplicate dossier, R & I record of initial submission verified vide letter No.F.1-11/2019-Reg-II dated 07-05-

		2020. Verification of initial and differential fee challans required)
	Pharmacological Group	Anti-rheumatics, NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1ml × 5 ampoules, As per SRO
	Approval status of product in Reference Regulatory Authorities	(ANSM France) PIROXICAM PFIZER 20 mg/1 ml, solution for injection in ampoule (IM)
	Me-too status	Salden 20mg Injection of M/s Danas Pharma (Reg.#080373)
	GMP status	Inspection for ground check/inspection of NOC for quota allocation of controlled substances conducted on 17-02-2022 submitted as evidence of GMP status of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Liquid Injectable (General ampoules only) section approved vide Licensing Division letter No.F.1-38/91-Lic (Vol-I) dated 10-08-2015. • Initially the Form-5 submitted by the firm was not in prescribed format. Moreover, the applicant name mentioned as Lawrance pharma (Pvt) Ltd. 10.5 Km Sheikhupura road, Lahore, while the brand (proprietary) name mentioned is Lawrcam Injection. • Firm resubmit Form 5 in prescribed format and rectify the applicant name and brand (proprietary name) as well. • The firm specified the route of administration as parenteral. The reference product is for IM use. • Firm provided complete manufacturing outlines for the applied formulation. • Firm submitted fee of Rs: 7500/- vide online deposit slip No.31965800.
	Decision: Approved with innovator's specifications. • Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. **•Firm shall submit the differential fee of Rs. 22,500 for correction/pre-approval change in Form 5 (correction/change of applicant name), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** **•Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
881.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	JASTINE SYRUP (Ebastine 5mg/5ml)
	Composition	Each 5ml contains: Ebastine…...5mg
	Diary No. Date of R & I & fee	Dy. No. 274 dated 24-03-2009, Rs. 8,000/- dated Challan (not provided) Dy. No. 267 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0523895 dated 10-12-2015 (Photocopy), (Duplicate dossier, R & I cover letter copy of initial submission not provided Verification of initial and differential fee submissions along with challans required)
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ebastel oral solution 1mg/ml of Almirall, (AEMPS – CIMA Spain Approved)
	Me-too status	Fystine Liquid Syrup of M/s Fynk Pharmaceuticals, Lahore. (Reg. # 077173)

	GMP status	Inspection for ground check/inspection of NOC for quota allocation of controlled substances conducted on 17-02-2022 submitted as evidence of GMP status of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of relevant section by Licensing Division, DRAP Islamabad. • Provide DRAP R & I stamped cover letter of initial submission of application form along with fee challan. • Product is non-pharmacopoeia and firm has claimed manufacturer specifications. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Verification of DRAP R & I record of initial submission of registration application along with fee.**	
882.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	JAWAFLOX DRY SUSPENSION (125mg/5ml)
	Composition	Each 5ml contains: Ciproflxocin (as hydrochloride) …...125mg
	Diary No. Date of R & I & fee	Dy. No. 5280 dated 11-05-2011, Rs. 8,000/- dated 11-05-2011 Challan (Photocopy) Dy. No. 273 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0160877 dated 10-12-2015 (Photocopy), (Duplicate dossier, R & I record of initial submission verified vide letter No.F.1-11/2019-Reg-II dated 07-05-2020. Verification of initial and differential fee challans required)
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Ciproxin 250mg/5ml granules and solvent for oral suspension 5 ml suspension after reconstitution (1 measuring spoon) contains 250 mg ciprofloxacin. 2.5 mL suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin.
	Me-too status	Ciplozin Dry Powder Suspension 125mg/5ml of M/s KBR Pharmaceuticals, Hattar (Reg.No. 103023)
	GMP status	Inspection for ground check/inspection of NOC for quota allocation of controlled substances conducted on 17-02-2022 submitted as evidence of GMP status of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Dry Powder Suspension (General antibiotic) Section approved vide Licensing Division letter No.F.1-38/91-Lic (Vol-II) (M-212) dated 18-06-2008. • Registration Board in its 269th meeting decided as follows: Keeping in view the following statement written in Qualitative and quantitative composition "2.5 ml suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin" and domestic conditions for difficulties in dispensing 250mg/5ml suspension for children under 2 years of age, Registration Board decided to approve the formulation of ciprofloxacin

		125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA. • Firm revised label claim as: Each 5ml of the reconstituted suspension contains: Ciprofloxacin (as hydrochloride) (taste mask granules) …….125mg • Firm revised master formulation and manufacturing outlines, in line with reference product which is in the form of taste mask granules. • Firm specified the source/vendor of taste-mask granules as M/s Vision Pharmaceuticals, Islamabad. • Firm has provided GMP certificate of pellets source/supplier (M/s Vision Pharmaceuticals, Islamabad) that is valid till 09-05-2022. • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2ºC and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data sheets conducted at 40 ^{0}C ± 2 ºC and 75%RH ± 5%RH of three batches for 06 months with testing points as 0, 3, 6, 9, 12, 18, 24 & 36 months (for Long term stability studies) and 0, 1, 2, 3 & 6 months (for Accelerated Stability Conditions). • Firm revised finished drug product specifications as per official monograph (USP). • Firm submitted fee of Rs: 7500/- vide online deposit slip No.98219470485. • The firm has to submit differential fee Rs: 22,500/- as the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 is 30,000. Since firm has revised the formulation/composition from powder form to taste mask granules (ready to fill).
	Decision: Approved with revised label claim as: **Each 5ml of the reconstituted suspension contains:** **Ciprofloxacin (as hydrochloride) …….125mg** **(As taste mask granules)** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **The firm shall ensure the supply of Ciprofloxacin granules for oral suspension along with the solvent/diluent as per innovator's product in compliance with decision of 290th meeting of Drug Registration Board.** • **Firm shall submit the differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of formulation from powder to taste-mask granules), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration letter will be issued after submission of GMP audit report within last three years.**	
883.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	BETSAL CREAM
	Composition	Each gm contains: Betamethasone dipropionate…… 0.5mg Salicylic acid…….. 30mg
	Diary No. Date of R & I & fee	Dy. No. 5286 dated 11-05-2011, Rs. 8,000/- dated 11-05-2011 Challan (Photocopy) Dy. No. 282 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0542088 dated 10-12-2015 (Photocopy), (Duplicate dossier, R & I record of initial submission verified vide letter No.F.1-11/2019-Reg-II dated 07-05-2020. Verification of initial and differential fee challans required)

	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	5gm, 15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved products are cutaneous solution and ointment: Diprosalic Scalp Application 0.05% w/w / 2% w/w, cutaneous solution, Betamethasone Dipropionate 0.064% w/w* (* equivalent to 0.05% Betamethasone) Salicylic Acid 2.00% w/w. Diprosalic 0.05% w/w / 3% w/w Ointment, Betamethasone Dipropionate 0.064% w/w* (* equivalent to 0.05% Betamethasone) Salicylic Acid 3.00% w/w.
	Me-too status	Novasalic Ointment Contains: - Betamethasone (as Dipropionate) ...0.05% w/w Salicylic Acid….3.0% w/w of M/s Mass Pharma, Lahore. Reg.No. 024370
	GMP status	GMP certificate granted on 06/07/2020
	Remarks of the Evaluator (PEC-XVII)	• Cream/ointment (General) section approved vide Licensing Division letter No.F.1-38/91-Lic (Vol-I) (M-227) dated 17-06-2011. • Initially firm applied product was "Betsal cream". The firm was asked to provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were approved by Registration Board in its 275th meeting or else revise label claim/formulation as per reference product and revise master formulation, label claim and manufacturing outlines accordingly. The firm clarified that the applied formulation is ointment but mistakenly mentioned as cream in application form. • Firm submitted fee of Rs: 7500/- vide online deposit slip No.986857453. • The firm has to submit differential fee Rs: 22,500/- as the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 is 30,000. Since firm has revised the formulation/composition from cream to ointment as per reference product. • Evidence of availability of separate dispensing facility for steroidal materials required.
	Decision: Approved with revised label claim as: **Each gm ointment contains:** **Betamethasone (as Dipropionate) ..... 0.5mg (0.05% w/w)** **Salicylic Acid……. 30mg (3.0% w/w)** • **Registration Board further decided that registration letter will be issued upon submission of following:** • **Verification of fee challan as per decision of 285th meeting of Registration Board.** • **Submission of differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Evidence of availability of separate dispensing facility for steroidal materials.**	
884.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	ACAID CREAM (0.1% w/w)
	Composition	Each gm contains: Adapalene…… 1mg
	Diary No. Date of R & I & fee	Dy. No.5264 dated 11-05-2011, Rs. 8,000/- dated 11-05-2011 Challan (Photocopy)

		Dy. No. 294 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0523889 dated 10-12-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-ance
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved, Differin 0.1% w/w Cream (1g cream contains 1mg adapalene)
	Me-too status	Redap 0.1% Cream of M/s Evolution pharmaceuticals, Islamabad. (Reg. No. 101639)
	GMP status	GMP certificate granted on 06/07/2020
	Remarks of the Evaluator (PEC-XVII)	• Cream/ointment (General) section approved vide Licensing Division letter No.F.1-38/91-Lic (Vol-I) (M-227) dated 17-06-2011. • Initially the brand (proprietary) name mentioned in application form as "JDPENE", while in fee challans, cover letters and enclosure, the name mentioned is ACAID CREAM. Firm clarified that the correct name is "Acaid cream" and JDPENE mentioned by mistake. The firm revised Form 5 with correct brand (proprietary) name. • Firm has claimed manufacturer specifications, however, official monograph available in BP. • The firm has submitted fee of Rs:7500/- vide online deposit slip No.12090631814 for revision of finished drug product specifications.
	Decision: Approved with BP specifications. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
885.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	ISORID GEL (0.05% w/w)
	Composition	Each gm contains: Isotretinoin…… 0.5mg
	Diary No. Date of R & I & fee	Dy. No. 5297 dated 11-05-2011, Rs. 8,000/- dated 11-05-2011 Challan (Photocopy) Dy. No. 287 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0542021 dated 10-12-2015 (Photocopy), (Duplicate dossier, R & I record of initial submission verified vide letter No.F.1-11/2019-Reg-II dated 07-05-2020. Verification of initial and differential fee challans required)
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	5gm, 15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Isotrex Gel, (MHRA approved) The active substance is isotretinoin 0.05% w/w (0.05 g per 100 g gel).
	Me-too status	Maso Gel of M/s Masfa Industries, Lahore. (Reg. No. 101589)
	GMP status	Inspection for ground check/inspection of NOC for quota allocation of controlled substances conducted on 17-02-2022 submitted as evidence of GMP status of the firm.

	Remarks of the Evaluator (PEC-XVII)	• The firm has provided Cream/ointment (General) section approved vide Licensing Division letter No.F.1-38/91-Lic (Vol-I) (M-227) dated 17-06-2011 as evidence of availability of required manufacturing facility for gel. • Initially the brand (proprietary) name mentioned in application form as "T-IOSKIN GEL", while in fee challans, cover letters and enclosure, the name mentioned is ISORID GEL. Firm clarified that the correct name is "ISORID GEL" and T-IOSKIN GEL mentioned by mistake. The firm revised Form 5 with correct brand (proprietary) name. • Clarification regarding fee submission as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 is required.
	Decision: Approved. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
886.	Name and address of manufacturer/ Applicant	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	POLYWAX PLUS OINTMENT
	Composition	Each gm contains: Polymyxine B Sulphate…… 10000 units Bacitracin Zinc…… 500 units Lignocaine…… 40mg
	Diary No. Date of R & I & fee	Dy. No. 5290 dated 11-05-2011, Rs. 8,000/- dated 11-05-2011 Challan (Photocopy) Dy. No. 261 dated 16-12-2015 Differential fee Rs. 12,000/- vide challan No.0542087 dated 10-12-2015 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	5gm, 15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Polyfax plus ointment of M/s GSK. Registration No.023511 Needs confirmation.
	GMP status	Inspection for ground check/inspection of NOC for quota allocation of controlled substances conducted on 17-02-2022 submitted as evidence of GMP status of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Cream/ointment (General) section approved vide Licensing Division letter No.F.1-38/91-Lic (Vol-I) (M-227) dated 17-06-2011. • Initially the brand (proprietary) name mentioned in application form as "JAWABACT CREAM", while in fee challans, cover letters and enclosure, the name mentioned is POLYWAX PLUS OINTMENT. Firm clarified that the correct name is "POLYWAX PLUS OINTMENT" and JAWABACT CREAM mentioned by mistake. The firm revised Form 5 with correct brand (proprietary) name.

		• The firm was asked to provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else revise label claim/composition as per reference product. The firm revised the label claim as: Each gm contains: Polymyxine B Sulphate…… 5000 units Bacitracin Zinc…… 500 units Neomycin (as Sulphate) ……3.5mg Lidocaine…… 40mg • The firm has submitted fee of Rs:7500/- vide online deposit slip No.66819852739 for above revision.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Submission of GMP audit report from QA&LT Division, valid within last three years.**	
887.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	MEDVERINE 135mg tablet
	Composition	Each film-coated tablet contains: - Mebeverine Hydrochloride ……135mg
	Diary No. Date of R & I & fee	Dy. No. 4466 dated 14-04-2011, Rs. 8,000/- dated 14-04-2011 (Challan photocopy) Dy. No.34 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527626 dated 15-03-2016. (Duplicate dossier, R & I verified"
	Pharmacological Group	Anticholinergics / anti-spasmodic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Mebeverine hydrochloride 135mg Film-coated Tablets)
	Me-too status	Mebfolds Tablet 135mg of M/s WeatherFolds, Hattar. Reg. No. 10281
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: "The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further".
	Remarks of the Evaluator (PEC-XVII)	• Initially the type of container/packaging materials was not mentioned. Firm specified the packaging materials as Alu-Alu blister in Unit Carton with leaflet. • Tablet (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
888.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	MONTIMED 10mg tablet

	Composition	Each film-coated tablet contains: - Montelukast (as sodium) ……10mg
	Diary No. Date of R & I & fee	Dy. No. 4467 dated 14-04-2011, Rs. 8,000/- dated 14-04-2011 (Challan photocopy) Dy. No.102 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527625 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Montelukast 10mg (as Montelukast Sodium) Film-coated tablets, MHRA approved.
	Me-too status	Dowkast 10mg tablet of M/s Seatle (Pvt) Ltd. Lahore Registration No. 103298
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised finished drug product specifications as per official monograph (USP) as in cover letter of initial submission, manufacturer specifications mentioned, while in duplicate dossier submitted, USP specifications are claimed. • Tablet (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License. • Firm has submitted fee of Rs: 7500/- vide online deposit slip No.10929481864 for above revision.
	Decision: Approved with USP specifications. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
889.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	ENTIVIRE 0.5mg tablet
	Composition	Each film-coated tablet contains: - Entecavir ……0.5mg
	Diary No. Date of R & I & fee	Dy. No.5755 dated 20-05-2011, Rs. 8,000/- dated 20-05-2011 (Challan photocopy) Dy. No.099 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527624 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Entecavir 0.5 mg film-coated tablets)
	Me-too status	Cavirent Tablet 0.5mg by M/s CKD Pharmaceuticals Reg#092969)

	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised label claim as: Each film-coated tablet contains: - Entecavir monohydrate eq. to Entecavir ……0.5mg and also revised master formulation/composition and manufacturing outlines accordingly. • Firm has submitted fee of Rs: 30000/- vide online deposit slip No.057783791070 for above revision. • Tablet (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved with USP specifications and revised label claim as: **Each film-coated tablet contains: -** **Entecavir monohydrate eq. to Entecavir ……0.5mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
890.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	IRO tablet
	Composition	Each tablet contains: - Iron (III) Polymaltose Complex ……100mg
	Diary No. Date of R & I & fee	Dy. No.2792 dated 23-06-2011, Rs. 8,000/- dated 23-06-2011 (Challan photocopy) Dy. No.37 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0502434 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-anaemic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(TGA Australia approved) Maltofer film-coated tablet (Iron polymaltose 370 mg Equivalent: Iron 100 mg) of Vifor Pharma, Australia
	Me-too status	Redroze Tablets of M/s Himont Pharma, Lahore. Registration No. 052752 Iriver 100mg Chewable Tablet of M/s Sigma Pharma International,Karachi. Registration No. 090941
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• In cover letters of initial and differential submission drug name mentioned as IRO Chewable tablets (Iron (III) Hydroxide Polymaltose complex….100mg, while label claim/composition in Form-5 mentioned as: Each tablet contains: - Iron (III) Polymaltose Complex ……100mg.

		The firm then revised label claim as: Each chewable tablet contains: - Iron (III) hydroxide Polymaltose Complex equivalent to elemental Iron ……100mg. The master formulation and manufacturing outlines were also revised accordingly. • Firm has submitted fee of Rs: 30000/- vide online deposit slip No.181546961808 for above revision. • Tablet (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved with revised label claim as: • **Each chewable tablet contains: -** **Iron (III) hydroxide Polymaltose Complex equivalent to elemental Iron ……100mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
891.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	IROFOL Chewable tablet
	Composition	Each tablet contains: - Iron (III) Polymaltose Complex eq. to Elemental Iron ……100mg Folic Acid…….0.35mg
	Diary No. Date of R & I & fee	Dy. No.259 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011 (Challan photocopy) Dy. No.96 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527620 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-anaemic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Fogyma 100mg/0.35mg chewable tablet of M/s Theramed Pharma, Lahore. Reg.No. 101702
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• In cover letters of initial and differential submission drug name mentioned as IROFOL Chewable tablets while label claim/composition in Form-5 mentioned as: Each tablet contains: - Iron (III) Polymaltose Complex eq. to Elemental Iron ……100mg Folic Acid…….0.35mg. The firm then revised label claim as: Each chewable tablet contains: - Iron (III) hydroxide Polymaltose Complex eq. to Elemental Iron ……100mg. Folic Acid…….0.35mg.

		The master formulation and manufacturing outlines were also revised accordingly. • Firm has submitted fee of Rs: 30000/- vide online deposit slip No.758376194 for above revision. • Ferrum Fol 100 mg / 350 micrograms, Chewable Tablets (Iron as Iron (III)-hydroxide polymaltose complex / folic acid) Vifor France (PIL available on google) • Tablet (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved with revised label claim as: • **Each chewable tablet contains: -** **Iron (III) hydroxide Polymaltose Complex eq. to Elemental Iron ……100mg.** **Folic Acid…….0.35mg.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
892.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	SPASNIL 4mg tablet
	Composition	Each tablet contains: - Tizanidine as HCl …….4mg
	Diary No. Date of R & I & fee	Dy. No.2697 dated 22-06-2011, Rs. 8,000/- dated 22-06-2011 (Challan photocopy) Dy. No.39 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0502416 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Alpha-2-Adrenergic agonist, muscle relaxant
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Zanaflex® Tablets uncoated (USFDA approved)
	Me-too status	Ternine Tablet 4mg of M/s Hiranis pharmaceuticals, Karachi. Reg.No. 103161
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group as "muscle relaxants, centrally acting agents, other centrally acting agents". • Firm has submitted fee of Rs: 7500/- vide online deposit slip No.90451827003 for above revision. • Tablet (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
893.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.

	Brand Name + Dosage Form + Strength	ALEMAX 70mg tablet
	Composition	Each tablet contains: - Alendronate Sodium as Sesquihydrate ……. 70mg
	Diary No. Date of R & I & fee	Dy. No.2700 dated 22-06-2011, Rs. 8,000/- dated 22-06-2011 (Challan photocopy) Dy. No.92 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527610 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Inhibitor of osteoclastmediated bone resorption
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	4's, 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved), Each tablet contains 70 mg alendronic acid (as sodium trihydrate), uncoated
	Me-too status	Entrate 70mg Tablet of M/s Genetics pharmaceuticals, Lahore. Reg.No. 098263
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised finished drug product specifications as per official monograph (USP). • Firm revised master formula and manufacturing outlines as per label claim for uncoated tablet. • Firm revised label claim as: Each tablet contains: - Alendronic acid (As sodium trihydrate) ……. 70mg • Firm has submitted fee of Rs: 30000/- vide online deposit slip No.70306387654 for above revision. • Tablet (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved with USP specifications and revised label claim as: **Each tablet contains: -** **Alendronic acid (As sodium trihydrate) ……. 70mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
894.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	ARTEMED DS DRY SUSPENSION
	Composition	Each 5ml of the reconstituted suspension contains: - Artemether……30mg Lumefantrine…….180mg
	Diary No. Date of R & I & fee	Dy. No.1637 dated 10-06-2011, Rs. 8,000/- dated 10-06-2011 (Challan photocopy), Dy.No.1637 dated 10-06-2011 (Section diary), Dy. No.96 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527614 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-malarial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mentioned strength in International Pharmacopoeia is 15 mg Artemether and 90 mg of Lumefantine per 5 ml.
	Me-too status	Artem Plus 30/180 Dry Suspension of Hilton Pharma, Karachi. Reg.No. 066963
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Type of container/packaging materials not mentioned by the firm. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Revise finished drug product specifications as per official monograph (International Pharmacopoeia). • Dry powder suspension (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License. For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: **•Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th.** **• Submission of GMP audit report from QA&LT Division, valid within last three years.**	
895.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	ARTEPIP DRY SUSPENSION
	Composition	Each 5ml of the reconstitution suspension contains: - Dihydroartemisinin …...15mg Piperaquine ……120mg
	Diary No. Date of R & I & fee	Dy. No.1612 dated 09-06-2011, Rs. 8,000/- dated 09-06-2011 (Challan photocopy) Dy. No.93 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527618 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-diarrheal
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	60ml, 30ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Euaria 15mg/120mg/5ml Powder for Oral Suspension of M/s Martin Dow, Karachi. Reg.No. 076463
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Revise pharmacological group as "Anti-malarial.

		• Provide evidence of availability of applied formulation in reference regulatory authorities adopted by the Registration Board in its 275th meeting. • Product is non-pharmacopoeial. • Dry powder suspension (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License. For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: **•Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th.** **• Revision of pharmacological group as "Anti-malarial".** **• Submission of GMP audit report from QA&LT Division, valid within last three years.** **• Submission of applicable fee, as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
896.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	CONAZOLE DRY SUSPENSION (40mg/ml)
	Composition	Each ml of the reconstitution suspension contains: - Voriconazole ……... 40mg
	Diary No. Date of R & I & fee	Dy. No.1610 dated 09-06-2011, Rs. 8,000/- dated 09-06-2011 (Challan photocopy) Dy. No.99 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527617 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-fungal
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	75ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Voriconazole Pfizer 40 mg/ml powder for oral suspension (MHRA approved)
	Me-too status	Voricon Suspension of M/s S.J & G. Fazul Ellahie, Karachi. Reg.No. 101423
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group as "Antimycotics for Systemic Use, triazole and tetrazole derivatives". • Firm claimed manufacture specifications, while the applied product is non-pharmacopoeial. • Firm submitted fee of Rs: 7500/- vide on-line deposit slip No.633303319526 for above revision. • Dry powder suspension (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved with innovator's specifications. **•Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** **•Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	

897.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals Plot No.249/A, Industrial triangle, Kahuta road, Islamabad.
	Brand Name + Dosage Form + Strength	ESOZOLE 20mg Capsule
	Composition	Each capsule contains: - Magnesium Trihydrate (enteric coated pellets) …...…20mg
	Diary No. Date of R & I & fee	Dy. No.4000 dated 05-06-2012, Rs. 8,000/- dated 05-06-2012 (Challan photocopy) Dy. No. 383 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0502438 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	Parko-Eprazole Capsule 20mg of M/s Parkar Pharma, Kotri. Registration No. 102819
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised label claim as: Each capsule contains: Esomeprazole (as Magnesium trihydrate enteric coated pellets) ……20mg • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Firm specified the source/vendor of Esomeprazole enteric coated pellets as M/s Vision Pharmaceuticals, Islamabad. • Firm has provided GMP certificate of pellets source/supplier (M/s Vision Pharmaceuticals, Islamabad) that is valid till 09-05-2022. • Firm provided CoA of Esomeprazole magnesium enteric coated pellets 8.5%. • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2^{o}C and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data sheets conducted at 40 ^{0}C ± 2 ^{o}C and 75%RH ± 5%RH of three batches for 06 months with testing points as 0, 3, 6, 9, 12, 18, 24 & 36 months (for Long term stability studies) and 0, 3 & 6 months (for Accelerated Stability Conditions). • Firm has submitted fee of Rs: 7500/- vide on-line deposit slip No.01508481016 for label claim revision. • Capsule (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License. • Composition as per master formulation provided is: Each capsule contains: Esomeprazole (as Magnesium trihydrate enteric coated pellets 8.5%) ……20mg
	Decision: Approved with revised label claim as:	

	Each capsule contains: **Esomeprazole (as Magnesium trihydrate enteric coated pellets) ……20mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
898.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	OMED 40mg Capsule
	Composition	Each capsule contains: - Omeprazole enteric coated pellets eq. to Omeprazole……40mg
	Diary No. Date of R & I & fee	Dy. No.2696 dated 22-06-2011, Rs. 15,000/- dated 22-06-2011 (Challan photocopy) Dy. No.35 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0502436 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	Parkoprazole Capsule 40mg of M/s Parkar Pharma, Kotri. Registration No. 102818
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm specified the source/vendor of Omeprazole enteric coated pellets as M/s Vision Pharmaceuticals, Islamabad. • Firm has provided GMP certificate of pellets source/supplier (M/s Vision Pharmaceuticals, Islamabad) that is valid till 09-05-2022. • Firm provided CoA of Omeprazole enteric coated pellets 22.5%. • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2ºC and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data sheets conducted at 40 ^{0}C ± 2 ºC and 75%RH ± 5%RH of three batches for 06 months with testing points as 0, 3, 6, 9, 12, 18, 24 & 36 months (for Long term stability studies) and 0, 3 & 6 months (for Accelerated Stability Conditions). • Firm revised finished drug product specifications as per official monograph. • Firm has submitted fee of Rs: 7500/- vide on-line deposit slip No.5374182188 for above revision. • Capsule (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.

	Decision: Approved with USP specifications. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
899.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	TERMED CREAM 1% (w/w)
	Composition	Each gm contains: - Terbinafine as HCl ……. 1%
	Diary No. Date of R & I & fee	Dy. No.1641 dated 10-06-2011, Rs. 8,000/- dated 10-06-2011 (Challan photocopy), Dy.No.1641 dated 10-06-2011 (Section Diary), Dy. No.95 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527613 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Terbinafine hydrochloride 1% w/w
	Me-too status	Limisil Cream 1% of M/s GSK OTC (Pvt) Ltd., Petaro Road, Jamshoro. Registration No. 013210
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised label claim as per reference product as: Each gm contains: Terbinafine Hydrochloride…….10mg (1% w/w), along with revision of master formulation/composition. • Firm revised finished drug product specifications as per official monograph (Japanese Pharmacopoeia). • Firm has submitted fee of Rs: 30000/- vide on-line deposit slip No.905243553 for above revision. • Cream/ointment (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved with JP specifications and revised label claim as: **Each gm contains:** **Terbinafine Hydrochloride…….10mg (1% w/w)** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
900.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	Zois T CREAM 10% (w/w)
	Composition	Each gm cream contains: - Benzoyl Peroxide ……. 10%
	Diary No. Date of R & I & fee	Dy. No.2490 dated 20-06-2011, Rs. 8,000/- dated 20-06-2011 (Challan photocopy)

		Dy. No.94 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527612 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20gm, 40gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) 2.5%, 5% & 10% w/w gel, face wash 10% lotion, wash 4%, 5% cream
	Me-too status	Aknekream 5% Cream of M/s Werrick Pharmaceuticals, Islamabad. Registration No. 056767 Aknekream 10% Cream of M/s Werrick Pharmaceuticals, Islamabad. Registration No. 056768
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• The firm was asked to provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else revise label claim/composition as per reference product and submit revised master formulation accordingly as the evidence Zitfree Cream 10% could not be verified in USFDA database. • So, the firm revised label claim as: Each gm cream contains: - Benzoyl Peroxide ……. 5% (w/w) • Firm revised finished drug product specifications as per official monograph (BP) as in initial fee challan, the firm has claimed manufacturer specifications. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Cream/ointment (General) section available as per Licensing Division letter No.F.1-16/2005-Lic dated 15-06-2011 for issuance of Drug Manufacturing License.
	Decision: Approved with BP specifications and revised label claim as: **Each gm cream contains:** **Benzoyl Peroxide…….5% (w/w)** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from 10% to 5% w/w), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration letter will be issued after submission of GMP audit report from QA&LT Division, valid within last three years.**	
901.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	SCABINIL LOTION 1% (1% w/v)
	Composition	Each ml of lotion contains: - Lindane ……. 10mg (1% w/v)

	Diary No. Date of R & I & fee	Dy. No. dated 09-06-2011, Rs. 8,000/- dated 09-06-2011 (Challan photocopy) Dy. No.95 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527616 dated 15-03-2016. (Duplicate dossier, R & I record of initial submission could not be verified)
	Pharmacological Group	Anti-scabies
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved, status Discontinued Health Canada (Cancelled post market)
	Me-too status	Scafin Lotion 1% w/v of M/s Pharmasol Lahore. Registration No. 099703
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as: The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised finished drug product specifications as per official monograph (USP) as in initial fee challan, the firm has claimed manufacturer specifications. • Lotion (General) Section approved vide Licensing Division letter No.F.1-16/2005-Lic dated 03-03-2022. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No.55245388027.
	Decision: Deferred for following: **•Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as approval status of applied formulation in USFDA & Health Canada is "discontinued" & "Cancelled post market" respectively.** **• Verification of R & I record of initial submission of registration application as the same could not be confirmed by the R & I Section.**	
902.	Name and address of manufacturer/ Applicant	M/s Medera Pharmaceuticals (Pvt.) Ltd. Plot No.2, Street No. N-4, National Industrial Zone, Rawat.
	Brand Name + Dosage Form + Strength	Climed-T Lotion
	Composition	Each ml of lotion contains: - Clindamycin as Phosphate……10mg
	Diary No. Date of R & I & fee	Dy. No.1613 dated 09-06-2011, Rs. 8,000/- dated 09-06-2011 (Challan photocopy) Dy. No.92 dated 18-03-2016, Differential fee Rs. 12,000/- dated 18-03-2016 vide challan No.0527615 dated 15-03-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) Cleocin T® (Each ml contains clindamycin phosphate equivalent to 10mg clindamycin).
	Me-too status	CDX-T T 1% Lotion of M/s Fresh Pharmaceutical, Islamabad. Registration No. 099902
	GMP status	Inspection report/CAPA report dated 19-07-2021 in lieu of inspection conducted on 03-11-2020, submitted by the firm. Remarks made by the FID as:

		The firm was inspected on 19-07-2021 and following improvements has been found made the firm and is satisfactory further improvement is a continuous process and firm is willing to improve further.
	Remarks of the Evaluator (PEC-XVII)	• The firm revised pharmacological group as "Anti-infectives for treatment of acne". • USP monograph for topical include solution, suspension, gel. The firm has claimed manufacturer specifications. • Lotion (General) Section approved vide Licensing Division letter No.F.1-16/2005-Lic dated 03-03-2022. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No.9934525740.
	Decision: Approved with BP specifications with submission of fee for change in specifications. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of GMP audit report valid within last three years.**	
903.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	CARB 40/5 Tablets
	Composition	Each film coated tablet contains: Telmisartan ……40mg Amlodipine as Besylate….5mg
	Diary No. Date of R & I & fee	Dy. No. dated 29-11-2010, Rs. 8,000/- dated 29-11-2010 (Challan photocopy dated 12-10-2010), Dy. No. dated 17-01-2017, Differential fee Rs. 12,000/- dated 03-01-2017 submitted vide deposit slip No.0569397 dated 01-12-2016. "Duplicate dossier, verification of R & I for initial and differential fee submission along with fee challans required".
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's & 14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) TWYNSTA® 40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg uncoated bi-layer tablet Boehringer Ingelheim International GmbH.
	Me-too status	Tiocardis-AM Tablet 40mg/5mg of M/s Atco laboratories, Karachi. Registration No. 098764
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised the label claim as: Each uncoated bi-layered tablet contains: Telmisartan ……40mg Amlodipine as Besylate….5mg, along with revision of composition/master formulation and manufacturing outlines. • Firm revised finished drug product specifications as per official monograph (USP). • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • With regard to availability of bi-layered compression machine, the firm replied as:

		We have the machine/equipment ZPW23 II (I.D # NQFC-P & M-TCM2) for the manufacturing of bi-layered tablets and are manufacturing several bi-layered tablets in this section. The firm provided copy of purchase invoice for ZPW23 compression machine and Good Declaration (GD-I) certificate. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No.9226887964 for revision of finished drug product specifications. • The firm submitted remaining fee of Rs: 22,500/- vide online deposit slip No.933234663.
	Decision: Deferred for verification of R & I record of initial submission of registration application as the same could not be verified by the R & I Section	
904.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	CARB 80/5 Tablets
	Composition	Each film coated tablet contains: Telmisartan ……80mg Amlodipine as Besylate….5mg
	Diary No. Date of R & I & fee	Dy. No.244 dated 29-11-2010, Rs. 8,000/- dated 29-11-2010 (Challan photocopy dated 12-10-2010), Dy. No.1594 dated 17-01-2017, Differential fee Rs. 12,000/- dated 03-01-2017 submitted vide deposit slip No.0569398 dated 01-12-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's & 14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) TWYNSTA® 40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg uncoated bi-layer tablet Boehringer Ingelheim International GmbH.
	Me-too status	Tiocardis-AM Tablet 80mg/5mg of Atco Pharma, Karachi. Registration No. 098766
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised the label claim as: Each uncoated bi-layered tablet contains: Telmisartan ……80mg Amlodipine as Besylate….5mg, along with revision of composition/master formulation and manufacturing outlines accordingly. • Firm revised finished drug product specifications as per official monograph (USP). • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • With regard to availability of bi-layered compression machine, the firm replied as: We have the machine/equipment ZPW23 II (I.D # NQFC-P & M-TCM2) for the manufacturing of bi-layered tablets and are manufacturing several bi-layered tablets in this section. The firm provided copy of purchase invoice for ZPW23 compression machine and Good Declaration (GD-I) certificate.

		• The firm has submitted fee of Rs: 7500/- vide online deposit slip No.21709381 for revision of finished drug product specifications. • The firm submitted remaining fee of Rs: 22,500/- vide online deposit slip No. 8929809185.
	Decision: Approved with USP specifications and revised label claim as: **Each uncoated bi-layered tablet contains:** **Telmisartan ……80mg** **Amlodipine as Besylate….5mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of Installation qualification, performance qualification and operational qualification of bi-layered tablet compression machine.**	
905.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	CARB 40/10 Tablets
	Composition	Each film coated tablet contains: Telmisartan ……40mg Amlodipine as Besylate….10mg
	Diary No. Date of R & I & fee	Dy. No.240 dated 29-11-2010, Rs. 8,000/- dated 29-11-2010 (Challan photocopy dated 12-10-2010), Dy. No.1594 dated 17-01-2017, Differential fee Rs. 12,000/- dated 03-01-2017 submitted vide deposit slip No.0569399 dated 01-12-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's & 14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) TWYNSTA® 40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg uncoated bi-layer tablet Boehringer Ingelheim International GmbH.
	Me-too status	Tiocardis-AM Tablet 40mg/10mg of Atco Pharma, Karachi. Registration No. 098765
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised the label claim as: Each uncoated bi-layered tablet contains: Telmisartan ……40mg Amlodipine as Besylate….10mg, along with revision of composition/master formulation and manufacturing outlines. • Firm revised finished drug product specifications as per official monograph (USP). • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • With regard to availability of bi-layered compression machine, the firm replied as: We have the machine/equipment ZPW23 II (I.D # NQFC-P & M-TCM2) for the manufacturing of bi-layered tablets and are manufacturing several bi-layered tablets in this section. The firm provided copy of purchase invoice for ZPW23 compression machine and Good Declaration (GD-I) certificate.

		• The firm has submitted fee of Rs: 7500/- vide online deposit slip No.3845014749 for above revision. • The firm submitted remaining fee of Rs: 22,500/- vide online deposit slip No. 289447364517.
	Decision: Approved with USP specifications and revised label claim as: **Each uncoated bi-layered tablet contains:** **Telmisartan ……40mg** **Amlodipine as Besylate….10mg** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Registration letter will be issued after submission of Installation qualification, performance qualification and operational qualification of bi-layered tablet compression machine.**	
906.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	PROVA 100mg Tablet
	Composition	Each tablet contains: Modafinil……...100mg
	Diary No. Date of R & I & fee	Dy. No.09 dated 01-01-2011, Rs. 8,000/- dated 01-01-2011 (Challan photocopy provided), Dy. No.573 dated 08-02-2017, Differential fee Rs. 12,000/- dated 08-02-2017 submitted vide deposit slip No.0576421 dated 24-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Wakefulness-promoting agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's & 20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) PROVIGIL® (modafinil) uncoated tablets of Teva pharmaceuticals.
	Me-too status	Velert 100mg Tablet of M/s Bio-Labs, Islamabad. Registration No. 093256
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group as "Psychostimulant, centrally acting sympathomimetic". • Firm revised finished drug product specifications as per official monograph (USP). • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No.5611385497 for above revision.
	Decision: Approved with USP specifications. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
907.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	PROVA 200mg Tablet
	Composition	Each tablet contains: Modafinil……...200mg
	Diary No. Date of R & I & fee	Dy. No.24 dated 04-01-2011, Rs. 8,000/- dated 04-01-2011 (Challan photocopy provided), Dy.No.573 dated 08-02-2017, Differential fee Rs. 12,000/- dated 08-02-2017 submitted vide deposit slip No.0576425 dated 24-01-2017. "Duplicate dossier, R & I verified"

	Pharmacological Group	Wakefulness-promoting agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's & 20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) PROVIGIL® (modafinil) 100 & 200mg uncoated tablets of Teva pharmaceuticals.
	Me-too status	Velert 200mg Tablet of M/s Bio-Labs, Islamabad. Registration No. 093257
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Revise pharmacological group as "Psychostimulant, centrally acting sympathomimetic". • Revise finished drug product specifications as per official monograph (USP). • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No.5097691571 for above revision.
	Decision: Approved with USP specifications. **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
908.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	NALGESIC 4mg Tablet
	Composition	Each film-coated tablet contains: Lornoxicam …….4 mg
	Diary No. Date of R & I & fee	Dy. No.258 dated 19-04-2011, Rs. 8,000/- dated 19-04-2011 (Challan photocopy dated 16-03-2011 provided), Dy. No.1071 dated 13-02-2017, Differential fee Rs. 12,000/- dated 10-02-2017 submitted vide deposit slip No.0576429 dated 03-02-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-rheumatics (anti-inflammatory agents)
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	5's, 10's & 20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(Xefo 4 mg - film-coated tablets of Takeda, Denmark
	Me-too status	Xefast 4mg tablet of M/s PharmEvo, Karachi. Reg.No. 067376
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group as "Anti-rheumatics, Anti-inflammatory, non-steroids". • Firm revised master formulation by replacing Methylene chloride with IPA as solvent for film-coating. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020.

		• The firm has submitted fee of Rs: 7500/- vide online deposit slip No.8806668479 for above revision.
	Decision: Approved with innovator's specifications. **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
909.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	NALGESIC 8mg Tablet
	Composition	Each film-coated tablet contains: Lornoxicam …….8 mg
	Diary No. Date of R & I & fee	Dy. No.252 dated 19-04-2011, Rs. 8,000/- dated 19-04-2011 (Challan photocopy dated 16-03-2011 provided), Dy.No.1071 dated 13-02-2017, Differential fee Rs. 12,000/- dated 10-02-2017 submitted vide deposit slip No.0576430 dated 03-02-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-rheumatics (anti-inflammatory agents)
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	5's, 10's & 20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(Xefo 8 mg - film-coated tablets of Takeda, Denmark
	Me-too status	Xefast 8mg tablet of M/s PharmEvo, Karachi. Reg.No. 067377
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group as "Anti-rheumatics, Anti-inflammatory, non-steroids". • Firm revised master formulation by replacing Methylene chloride with IPA as solvent for film-coating. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No.3162453690 for above revision.
	Decision: Approved with innovator's specifications. **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
910.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	NITZIX 500mg Tablet
	Composition	Each film-coated tablet contains: Nitazoxanide……...500mg
	Diary No. Date of R & I & fee	Dy. No.306 dated 25-04-2011, Rs. 8,000/- dated 25-04-2011 (Challan photocopy dated 16-03-2011 provided), Dy. No.573 dated 08-02-2017, Differential fee Rs. 12,000/- dated 08-02-2017 submitted vide deposit slip No.0576422 dated 24-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Synthetic anti-protozoal agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's & 20's, As per SRO

	Approval status of product in Reference Regulatory Authorities	(USFDA approved) ALINIA® (nitazoxanide) film-coated tablets Romark, L.C.
	Me-too status	Tyzonix Tablet 500mg of M/s Wnsfield Hattar. Reg.No. 102916
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised master formulation by replacing Methylene chloride with IPA as solvent for film-coating. • Firm revised finished drug product specifications from manufacturer to innovators specifications. • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No.070731299429 for above revision.
	Decision: Approved with innovator's specifications. **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
911.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	NITZIX Suspension (100mg/5ml)
	Composition	Each 5ml when reconstituted as directed contains: Nitazoxanide……...100mg
	Diary No. Date of R & I & fee	Dy. No.305 dated 25-04-2011, Rs. 8,000/- dated 25-04-2011 (Challan photocopy dated 16-03-2011 provided), Dy. No.573 dated 08-02-2017, Differential fee Rs. 12,000/- dated 08-02-2017 submitted vide deposit slip No.0576423 dated 24-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Synthetic anti-protozoal agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30ml & 60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) ALINIA® (nitazoxanide) for oral Suspension 100 mg/5 mL Romark, L.C.
	Me-too status	Picato Dry Suspension 100mg/5ml of Pakistan pharmaceutical products, Karachi. Reg.No. 102867
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm has claimed manufacturer specifications, while product is non-pharmacopoeial. • Dry powder (General/antibiotic) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovator's specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	

912.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	RELIEFAL SINUS Tablet
	Composition	Each tablet contains: Paracetamol……...500 mg Pseudoephedrine HCl……30mg
	Diary No. Date of R & I & fee	Dy. No.356 dated 18-10-2011, Rs. 8,000/- dated 17-10-2011 (Challan photocopy dated 03-08-2011 provided), Dy. No.1594 dated 17-01-2017, Differential fee Rs. 12,000/- dated 03-01-2017 submitted vide deposit slip No.0569400 dated 01-12-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Analgesic, antihistamine
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's & 30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved as (Panadol Cold & Sinus 500mg / 30mg (A bilayer (white/blue) film coated capsule shaped tablet). TGA Approved as (Panadol Sinus relief original formula white capsule-shaped uncoated tablet).
	Me-too status	Couldn't be confirmed
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• Firm was asked to provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. The replied that generic/me-too for the applied formulation is not available. • Firm revised master formulation by replacing Methylene chloride with IPA as solvent for film-coating. • Firm revised finished drug product specifications as per official USP monograph for Acetaminophen and Pseudoephedrine Hydrochloride Tablets • Tablet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No. 1050256175 for above revision.
	Decision: Deferred for following: **•Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines of 293rd meeting of Drug Registration Board.**	
913.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name + Dosage Form + Strength	STROMAX Sachet
	Composition	Each sachet contains: Strontium ranelate …….2 gm
	Diary No. Date of R & I & fee	Dy. No.255 dated 19-04-2011, Rs. 8,000/- dated 19-04-2011 (Challan photocopy dated 16-03-2011 provided), Dy. No.1593 dated 17-01-2017, Differential fee Rs. 12,000/- dated 17-01-2017 submitted vide deposit slip No.0576418 dated 05-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Osteoporosis
	Type of Form	Form-5

	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	7's & 14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Strontium Ranelate Aristo 2 G Granules for Oral Suspension (MHRA Approved)
	Me-too status	Orinta 2gm Sachet of Wnsfield pharmaceuticals, Hattar. Reg. No. 075590
	GMP status	Panel inspection for grant of cGMP certificate conducted on 27-05-2022 with conclusion as: Based on the people met, documents reviewed and considering the observations made, panel recommends the grant of GMP certificate in favor of M/s Nabi Qasim Indsutries (Pvt.) Ltd. Korangi Industrial Area, Karachi.
	Remarks of the Evaluator (PEC-XVII)	• In cover letter for differential fee submission and differential fee challan, the product name mentioned is "Siromax Sachet", while the applied product is "Stromax Sachet". The firm regretted and termed it as "typographical mistake". The R & I record (Dy.No.255 dated 19-04-2011) showed the applied product as "Stromax sachet" • Firm revised pharmacological group as "Drugs affecting bone structure and mineralization". • Firm revised finished drug product specifications from manufacturer to Innovator's specifications. • Sachet (General) Section available as per DML renewal letter No.F.2-20/85-Lic (Vol-V) dated 27-04-2020. • The firm has submitted fee of Rs: 7500/- vide online deposit slip No. 0774897827 for above revision.
	Decision: Approved with innovator's specifications. **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
914.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	PRELIN Capsule
	Composition	Each capsule contains: Pregabalin……75mg
	Diary No. Date of R & I & fee	Dy. No. dated 06-03-2009, Rs. 8,000/- dated 06-03-2009. Dy. No. dated 17-03-2014, Differential fee Rs. 12,000/- dated 17-03-2014. "Duplicate dossier, verification of R & I for initial and differential fee submission along with fee challans required".
	Pharmacological Group	GABA analogue
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica (Pregabalin) capsule 75mg (USFDA approved)
	Me-too status	Pregra 75mg Capsule of M/s Mega pharmaceuticals, Lahore. Reg. No. 100786.
	GMP status	GMP certificate dated 27-07-2021 issued on the basis of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator (PEC-XVII)	• Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • R & I record for initial submission could not be found. The cover letter of initial submission does not bear R & I stamp. Only has statistical officer stamp for 8000/- fee submission dated 06-03-2009.

		• Capsule section (General) available as per DML renewal inspection report conducted on 30-05-2018 & 01-06-2018. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for verification of R & I record of registration application submission as the same could not be verified by R & I Section.	
915.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	NEURAL Syrup (500mg/5ml)
	Composition	Each 5ml contains: Citicoline as Sodium…500mg
	Diary No. Date of R & I & fee	Dy. No.8628 dated 22-09-2010, Rs. 8,000/- dated 22-09-2010. Dy. No. dated 06-12-2018, Differential fee Rs. 12,000/- vide challan No.0796978 dated 28-11-2018. "Duplicate dossier, R & I verified"
	Pharmacological Group	Neurotropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Somazine 100 mg / ml oral solution. CIMA Spain approved
	Me-too status	E-Citi Syrupof M/s English pharmaceuticals, Lahore. Registration No. 100526
	GMP status	GMP certificate dated 27-07-2021 issued on the basis of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator (PEC-XVII)	• Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • Liquid Syrup Section (General) mentioned in Licensing Division letter No.F.1-28/93-Lic dated 30-06-2020 for renewal of DML. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovator's specifications. Registration board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
916.	Name and address of manufacturer/ Applicant	M/s Getz Pharma (Pvt) Limited, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LINA 5mg Tablet
	Composition	Each film-coated tablet contains: Linagliptin…….5 mg
	Diary No. Date of R & I & fee	Dy. No.621 dated 03-05-2012, Rs: 15000 /- dated 02-05-2012 (Challan photocopy dated 25-04-2012 provided) Dy. No. 311 dated 12-10-2015, Differential fee Rs: 35,000/- dated 12-10-2015 vide challan No.0232390 dated 12-10-2015. Dy.No.21154-R & I dated 27-07-2022, Differential fee Rs: 25,000/- vide online deposit slip No.7421014973 (original). "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-diabetic (Dipeptidyl peptidase 4 inhibitor)
	Type of Form	Form-5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRADJENTA® 5mg film-coated tablet, Boehringer Ingelheim International GmbH. (USFDA approved)

	Me-too status	Trajenta 5mg Film Coated tablet imported by M/s AGP, Karachi. Reg. No. 078139 manufactured by Boehringer Ingelheim, USA
	GMP status	GMP certificate issued on 17-01-2022 based on evaluation conducted on 13-01-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.2-5/86-Lic (Vol-II) dated 30-10-2019 for renewal of Drug Manufacturing License. • Firm has claimed manufacturer specifications. • With reference to stability study data submission as per guidelines provided in 293rd meeting of Drug Registration Board, the firm has informed vide letter RA-QR/196/0822 dated 10-08-2022 that the stability studies for the product have already been initiated and will be submitted upon completion of 6 months intervals of long term and accelerated stability data. • R & I record verified. Details incorporated in relevant column above. Firm also submitted further differential fee of Rs: 25,000/- on 20-07-2022 vide online deposit slip. 7421014973. • Patent related issues of Linagliptin containing products decided in 297th meeting of RB as: After detailed deliberations, Registration Board decided that grant of marketing authorization / registration has no linkage with patent status of the originator's product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court.
	Decision: Deferred for submission of stability study data as per guidelines of 293rd meeting of Registration Board.	
917.	Name and address of manufacturer/ Applicant	M/s Getz Pharma (Pvt) Limited, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LINAMET Tablet (2.5/500mg)
	Composition	Each film-coated tablet contains: Linagliptin…….2.5 mg Metformin hydrochloride……500mg
	Diary No. Date of R & I & fee	Dy. No. 622 dated 03-05-2012, Rs: 15000 /- dated 02-05-2012 (Challan photocopy dated 25-04-2012 provided) Dy. No. 311 dated 12-10-2015, Differential fee Rs: 35,000/- dated 12-10-2015 vide challan No.0232392 dated 12-10-2015. Dy.No.21156-R & I dated 27-07-2022, Differential fee Rs: 25,000/- vide online deposit slip No. 865155619203 (original). "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-diabetic (Dipeptidyl peptidase 4 inhibitor + Biguanide
	Type of Form	Form-5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	JENTADUETO® film-coated tablets 2.5 mg linagliptin/500 mg metformin HCl 2.5 mg linagliptin/850 mg metformin HCl 2.5 mg linagliptin/1000 mg metformin HCl of Boehringer Ingelheim International GmbH. (USFDA approved)
	Me-too status	NA

	GMP status	GMP certificate issued on 17-01-2022 based on evaluation conducted on 13-01-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.2-5/86-Lic (Vol-II) dated 30-10-2019 for renewal of Drug Manufacturing License. • Firm has claimed manufacturer specifications. • With reference to stability study data submission as per guidelines provided in 293rd meeting of Drug Registration Board, the firm has informed vide letter RA-QR/196/0822 dated 10-08-2022 that the stability studies for the product have already been initiated and will be submitted upon completion of 6 months intervals of long term and accelerated stability data. • R & I record verified. Details incorporated in relevant column above.Firm also submitted further differential fee of Rs: 25,000/- on 20-07-2022 vide online deposit slip. 0232392. • Patent related issues of Linagliptin containing products decided in 297th meeting of RB as: After detailed deliberations, Registration Board decided that grant of marketing authorization / registration has no linkage with patent status of the originator's product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court.
	Decision: Deferred for submission of stability study data as per guidelines of 293rd meeting of Registration Board.	
918.	Name and address of manufacturer/ Applicant	M/s Getz Pharma (Pvt) Limited, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LINAMET Tablet (2.5/850mg)
	Composition	Each film-coated tablet contains: Linagliptin…….2.5 mg Metformin hydrochloride……850mg
	Diary No. Date of R & I & fee	Dy. No.624 dated 03-05-2012, Rs: 15000 /- dated 02-05-2012 (Challan photocopy dated 25-04-2012 provided) Dy. No. 311 dated 12-10-2015, Differential fee Rs: 35,000/- dated 12-10-2015 vide challan No.0232393 dated 12-10-2015. Dy.No.21157-R & I dated 27-07-2022, Differential fee Rs: 25,000/- vide online deposit slip No. 152325838 (original). "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-diabetic (Dipeptidyl peptidase 4 inhibitor + Biguanide
	Type of Form	Form-5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	JENTADUETO® film-coated tablets 2.5 mg linagliptin/500 mg metformin HCl 2.5 mg linagliptin/850 mg metformin HCl 2.5 mg linagliptin/1000 mg metformin HCl of Boehringer Ingelheim International GmbH. (USFDA approved)
	Me-too status	NA
	GMP status	GMP certificate issued on 17-01-2022 based on evaluation conducted on 13-01-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.2-5/86-Lic (Vol-II) dated 30-10-2019 for renewal of Drug Manufacturing License.

		• Firm has claimed manufacturer specifications. • With reference to stability study data submission as per guidelines provided in 293rd meeting of Drug Registration Board, the firm has informed vide letter RA-QR/196/0822 dated 10-08-2022 that the stability studies for the product have already been initiated and will be submitted upon completion of 6 months intervals of long term and accelerated stability data. • R & I record is verified. Details incorporated in relevant column above.Firm also submitted further differential fee of Rs: 25,000/- on 20-07-2022 vide online deposit slip. 0232393. • Patent related issues of Linagliptin containing products decided in 297th meeting of RB as: After detailed deliberations, Registration Board decided that grant of marketing authorization / registration has no linkage with patent status of the originator's product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court.
	Decision: Deferred for submission of stability study data as per guidelines of 293rd meeting of Registration Board.	
919.	Name and address of manufacturer/ Applicant	M/s Getz Pharma (Pvt) Limited, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LINAMET Tablet (2.5/1000mg)
	Composition	Each film-coated tablet contains: Linagliptin…….2.5 mg Metformin hydrochloride……1000mg
	Diary No. Date of R & I & fee	Dy. No. 623 dated 03-05-2012, Rs: 15000 /- dated 02-05-2012 (Challan photocopy dated 25-04-2012 provided) Dy. No. 311 dated 12-10-2015, Differential fee Rs: 35,000/- dated 12-10-2015 vide challan No.0232391 dated 12-10-2015. Dy.No.21158-R & I dated 27-07-2022, Differential fee Rs: 25,000/- vide online deposit slip No. 6660667857 (original). "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-diabetic (Dipeptidyl peptidase 4 inhibitor + Biguanide
	Type of Form	Form-5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	JENTADUETO® film-coated tablets 2.5 mg linagliptin/500 mg metformin HCl 2.5 mg linagliptin/850 mg metformin HCl 2.5 mg linagliptin/1000 mg metformin HCl of Boehringer Ingelheim International GmbH. (USFDA approved)
	Me-too status	NA
	GMP status	GMP certificate issued on 17-01-2022 based on evaluation conducted on 13-01-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.2-5/86-Lic (Vol-II) dated 30-10-2019 for renewal of Drug Manufacturing License. • Firm has claimed manufacturer specifications. • With reference to stability study data submission as per guidelines provided in 293rd meeting of Drug Registration Board, the firm has informed vide letter

		RA-QR/196/0822 dated 10-08-2022 that the stability studies for the product have already been initiated and will be submitted upon completion of 6 months intervals of long term and accelerated stability data. • R & I record is verified. Details incorporated in relevant column above.Firm also submitted further differential fee of Rs: 25,000/- on 20-07-2022 vide online deposit slip. 6660667857. • Patent related issues of Linagliptin containing products decided in 297th meeting of RB as: After detailed deliberations, Registration Board decided that grant of marketing authorization / registration has no linkage with patent status of the originator's product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court.
	Decision: Deferred for submission of stability study data as per guidelines of 293rd meeting of Registration Board.	
920.	Name and address of manufacturer/ Applicant	M/s Hassan Pharmaceuticals (Pvt) Ltd. 99-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	RTM tablet
	Composition	Each tablet contains: Artemether…...20mg Lumefantrine….120mg
	Diary No. Date of R & I & fee	Dy. No. 12 dated 03-11-2010, Rs. 8,000/- dated 03-11-2010 (Original), Dy. No. 3202 dated 18-05-2017 Differential fee Rs: 12000/- dated 18-05-2017 vide deposit slip No. 0712155 (original). "Original dossier"
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	16's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Prequalified by WHO
	Me-too status	Ajmetlum Tablet 20/120mg of M/s AJM pharma, Karachi. Registration No. 103049
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) and Tablet Section (Quinolone) available as per DML renewal inspection report conducted on 13-03-2010. • Provide most recent/last GMP inspection report conducted within last 03 years. • Firm has claimed manufacturer specifications, while official monograph available in International Pharmacopoeia. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Confirmation of GMP compliance status from QA & LT Division, since production of the firm is suspended in all sections vide QA & LT Division letter No.F.4-3/96-QA dated 09-09-2022 on account of FID inspection report dated 28-06-2022.** • **Revision of finished drug product specifications as per official monograph (International pharmacopoeia).** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	

921.	Name and address of manufacturer/ Applicant	M/s Hassan Pharmaceuticals (Pvt) Ltd. 99-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	RTM DS tablet
	Composition	Each tablet contains: Artemether…...40mg Lumefantrine….240mg
	Diary No. Date of R & I & fee	Dy. No. 17 dated 03-11-2010, Rs. 8,000/- dated 03-11-2010 (Original), Dy. No. 3202 dated 18-05-2017 Differential fee Rs: 12000/- dated 18-05-2017 vide deposit slip No. 0712153 (original). "Original dossier"
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	16's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Prequalified by WHO
	Me-too status	Ajmetlum Tablet 40/240mg of M/s AJM pharma, Karachi. Registration No. 103050.
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) and Tablet Section (Quinolone) available as per DML renewal inspection report conducted on 13-03-2010. • Provide most recent/last GMP inspection report conducted within last 03 years. • Firm has claimed manufacturer specifications, while official monograph available in International Pharmacopoeia. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Confirmation of GMP compliance status from QA & LT Division, since production of the firm is suspended in all sections vide QA & LT Division letter No.F.4-3/96-QA dated 09-09-2022 on account of FID inspection report dated 28-06-2022.** • **Revision of finished drug product specifications as per official monograph (International pharmacopoeia).** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
922.	Name and address of manufacturer/ Applicant	M/s Hassan Pharmaceuticals (Pvt) Ltd. 99-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	MOXET 400mg tablet
	Composition	Each tablet contains: Moxifloxacin HCl equivalent to moxifloxacin….400mg
	Diary No. Date of R & I & fee	Dy. No. 15 dated 03-11-2010, Rs. 8,000/- dated 03-11-2010 (Original), Dy. No. 3202 dated 18-05-2017 Differential fee Rs: 12000/- dated 18-05-2017 vide deposit slip No. 0712157 (original). Original dossier (Both original & differential)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	5's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Oxef 400mg Tablet of M/s Parmedic laboratories, Lahore. Registration No. 100852
	GMP status	Updated GMP compliance status required.

	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) and Tablet Section (Quinolone) available as per DML renewal inspection report conducted on 13-03-2010. • Provide most recent/last GMP inspection report conducted within last 03 years. • Revise the label claim as per reference product: Each film-coated tablet contains: Moxifloxacin (as hydrochloride) …….400mg • Firm has claimed manufacturer specifications, while official monograph available in USP. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Confirmation of GMP compliance status from QA & LT Division, since production of the firm is suspended in all sections vide QA & LT Division letter No.F.4-3/96-QA dated 09-09-2022 on account of FID inspection report dated 28-06-2022.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Revision of label claim as per reference product as:** **Each film-coated tablet contains:** **Moxifloxacin (as hydrochloride) …….400mg** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
923.	Name and address of manufacturer/ Applicant	M/s Hassan Pharmaceuticals (Pvt) Ltd. 99-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	VOMA DONE 10mg tablet
	Composition	Each tablet contains: Domperidone……...10mg
	Diary No. Date of R & I & fee	Dy. No. 16 dated 03-11-2010, Rs. 8,000/- dated 03-11-2010 (Original), Dy. No. 3202 dated 18-05-2017 Differential fee Rs: 12000/- dated 18-05-2017 vide deposit slip No. 0712154 (original). Original dossier (Both original & differential)
	Pharmacological Group	Antidopaminergic, propulsives
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	50's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved both as un-coated & film-coated tablet. Motilium is film-coated tablet
	Me-too status	Oxef 400mg Tablet of M/s Parmedic laboratories, Lahore. Registration No. 100852
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) and Tablet Section (Quinolone) available as per DML renewal inspection report conducted on 13-03-2010. • Provide most recent/last GMP inspection report conducted within last 03 years. • Revise the label claim as per reference product: Each film-coated tablet contains: Domperidone maleate equivalent to Domperidone…… 10 mg. • Firm has claimed manufacturer specifications, while official monograph available in BP. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following:	

	• **Confirmation of GMP compliance status from QA & LT Division, since production of the firm is suspended in all sections vide QA & LT Division letter No.F.4-3/96-QA dated 09-09-2022 on account of FID inspection report dated 28-06-2022.** • **Revision of finished drug product specifications as per official monograph (BP).** • **Revision of label claim as per reference product as:** **Each film-coated tablet contains:** **Domperidone maleate equivalent to Domperidone ……10mg** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
924.	Name and address of manufacturer/ Applicant	M/s Hassan Pharmaceuticals (Pvt) Ltd. 99-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	FERRIMED 100mg tablet
	Composition	Each tablet contains: Iron (III) hydroxide polymaltose complex equivalent to elemental iron……...100mg
	Diary No. Date of R & I & fee	Dy. No. 18 dated 03-11-2010, Rs. 8,000/- dated 03-11-2010 (Original), Dy. No. 3202 dated 18-05-2017 Differential fee Rs: 12000/- dated 18-05-2017 vide deposit slip No. 0712156 (original). "Original dossier"
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Redroze Tablets of M/s Himont Pharma, Lahore. Registration No. 052752 Iriver 100mg Chewable Tablet of M/s Sigma Pharma International,Karachi. Registration No. 090941
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) and Tablet Section (Quinolone) available as per DML renewal inspection report conducted on 13-03-2010. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Provide most recent/last GMP inspection report conducted within last 03 years. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Confirmation of GMP compliance status from QA & LT Division, since production of the firm is suspended in all sections vide QA & LT Division letter No.F.4-3/96-QA dated 09-09-2022 on account of FID inspection report dated 28-06-2022.** • **Revision of label claim as:** **Each chewable tablet contains:** **Iron (III) hydroxide polymaltose complex equivalent to elemental iron……...100mg** • **Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
925.	Name and address of manufacturer/ Applicant	M/s Hassan Pharmaceuticals (Pvt) Ltd. 99-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	VOMA DONE suspension
	Composition	Each 1ml of oral suspension contains: Domperidone…...1mg

	Diary No. Date of R & I & fee	Dy. No. 19 dated 03-11-2010, Rs. 8,000/- dated 03-11-2010 (Original), Dy. No. 3202 dated 18-05-2017 Differential fee Rs: 12000/- dated 18-05-2017 vide deposit slip No. 0712152 (original). "Original dossier"
	Pharmacological Group	Antidopamingeric, propulsives
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	120ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Domperidone 1mg/ml Oral Suspension (MHRA approved)
	Me-too status	Doperdone Oral Suspension 1mg/ml of Hiranis Pharmaceuticals, Karachi. Registration No. 103162
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Liquid Section (Liquified suspension and syrups) available as per DML renewal inspection report conducted on 13-03-2010. • Provide most recent/last GMP inspection report conducted within last 03 years. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Confirmation of GMP compliance status from QA & LT Division, since production of the firm is suspended in all sections vide QA & LT Division letter No.F.4-3/96-QA dated 09-09-2022 on account of FID inspection report dated 28-06-2022.**	
926.	Name and address of manufacturer/ Applicant	M/s Hassan Pharmaceuticals (Pvt) Ltd. 99-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	FERRIMED Syrup
	Composition	Each 5ml contains: Iron (III) hydroxide polymaltose complex equivalent to elemental iron……...50mg
	Diary No. Date of R & I & fee	Dy. No. 14 dated 03-11-2010, Rs. 8,000/- dated 03-11-2010 (Original), Dy. No. 3202 dated 18-05-2017 Differential fee Rs: 12000/- dated 18-05-2017 vide deposit slip No. 0712151 (original). (Original dossier)
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	CK-Malt Syrup 50mg/5ml of M/s CKD Pharmaceuticals, Karachi. Registration No. 101106
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Liquid Section (Liquified suspension and syrups) available as per DML renewal inspection report conducted on 13-03-2010. • Provide most recent/last GMP inspection report conducted within last 03 years. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • For above revision, submit applicable fee as per

		notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: **• Confirmation of GMP compliance status from QA & LT Division, since production of the firm is suspended in all sections vide QA & LT Division letter No.F.4-3/96-QA dated 09-09-2022 on account of FID inspection report dated 28-06-2022.**	

b. Deferred Cases

927.	Name and address of manufacturer/ Applicant	Shrooq Pharmaceuticals (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	ZUCLO 25mg tablet
	Composition	Each film-coated tablet contains: Zuclopenthixol (as Dihydrochloride) ……...25mg
	Diary No. Date of R & I & fee	Dy.No.8386 dated 14-09-2010, Fee Rs: 8,000/-Dated 14-09-2010 (Challan photocopy dated 13-09-2010) Dy.No.407 dated 31-03-2015, Differential fee: Rs. 12,000 Dated 31-03-2015 vide challan No.0285719. "Duplicate dossier, R & I of initial submission verified from Section Diary"
	Pharmacological Group	Anti-psychotic drug
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Elana 25mg tablet of M/s Aries Pharmaceuticals, Peshawar. Registration No. 100385
	GMP status	Panel inspection for renewal of DML conducted on 26-10-2021 and 29-10-2021 and recommended renewal of DML. cGMP certificate issued based on inspection conducted for renewal of DML on 29-10-2021. Tablet Sections (General and quinolone) are mentioned in DML inspection report as well in GMP certificate.
	Remarks of the Evaluator (PEC-XVII)	• Firm provided analytical testing methods for the finished drug product as per official monograph and submitted requisite fee Rs: 7500/- vide on-line deposit slip No.600875794114. • Verification of R &I, initial and differential fee slips required.
	Decision of 316th DRB meeting:	• Deferred for verification of R & I diary No./date, fee challan as per decision of 285th meeting of Registration Board.
	Remarks of the Evaluator (PEC-XVII)	• Record of initial submission of application verified from Section Diary and differential fee submission verified by the R & I section. The diary no. and date for both initial application and differential fee submission incorporated in relevant column above.
	Decision: Approved. Registration board further decided to verify fee challans as per decision of 285th meeting of Registration Board.	
928.	Name and address of manufacturer/ Applicant	Shrooq Pharmaceuticals (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	CLOVIR 250mg tablet
	Composition	Each film-coated tablet contains: Famciclovir (USP) ……...250mg
	Diary No. Date of R & I & fee	Dy.No.9973 dated 27-10-2010, Fee Rs: 8,000/-Dated 27-10-2010 (Challan photocopy dated 26-10-2010) Dy.No.414 dated 31-03-2015, Differential fee: Rs. 12,000 Dated 31-03-2015 vide challan No.0299394.

		"Duplicate dossier, R & I of initial submission verified from Section Diary"
	Pharmacological Group	Anti-viral drug
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	21's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Flovir 250mg tablet by Maxitech pharma Pvt ltd. Karachi. Registration No. 083712
	GMP status	Panel inspection for renewal of DML conducted on 26-10-2021 and 29-10-2021 and recommended renewal of DML. cGMP certificate issued based on inspection conducted for renewal of DML on 29-10-2021. Tablet Sections (General and quinolone) are mentioned in DML inspection report as well in GMP certificate.
	Remarks of the Evaluator (PEC-XVII)	• The firm has claimed manufacturer specifications while drug product monograph is available in USP42-NF37 1S – 8688 and onward. • Verification of R &I, initial and differential fee slips required.
	Decision of 316th DRB meeting:	• Deferred for verification of R & I diary No./date, fee challan as per decision of 285th meeting of Registration Board.
	Remarks of the Evaluator (PEC-XVII)	• Record of initial submission of application verified from Section Diary and differential fee submission verified by the R & I section. The diary no. and date for both initial application and differential fee submission incorporated in relevant column above. • The firm has claimed manufacturer specifications while drug product monograph is available in USP42-NF37 1S – 8688 and onward.
	Decision: Approved with USP specifications. • **Registration board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
929.	Name and address of manufacturer/ Applicant	M/s. Xenon Pharmaceuticals (Pvt.) Ltd. 9.5 km Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	METHYDATE Oral Solution
	Composition	Each 5ml contains: Methylphenidate HCl….5mg
	Diary No. Date of R & I & fee	Dy. No.2522 dated 21/06/2011 Rs. 8,000/- (photocopy) R&I Verified Differential fee (photocopy) of Rs. 12,000/- submitted on 16/11/2015 Dy.No.1495 "Duplicate dossier, R & I verified".
	Pharmacological Group	Centrally Acting Sympathomimetics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	21's, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved (Methylin 5mg/5ml, SpecGx. LLC.
	Me-too status	Could not be confirmed
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.

	Remarks of the Evaluator	• International availability in the approved RRA and me-too status of the applied formulation could not be confirmed. • Psychotropic section approval letter issued by licensing division is required. • Firm applied with manufacturer's specification while the official monograph of applied formulation is present in USP.
	Decision of 312th DRB meeting:	Deferred for updated GMP status of the firm from QA&LT Division.
	Remarks of the Evaluator (PEC-XVII)	• The product is approved in US FDA as oral solution in strength of 5mg/5ml and 10mg/5ml. • Me-too/generic drug product could not be confirmed. • As per panel inspection for DML renewal and regularization of sections conducted on 11-02-2022, the firm has Oral Liquid (Psychotropic Section) available. • Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML. • Product official monograph not available.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines of 293rd meeting of Registration Board along with submission of updated master formulation, manufacturing process, updated drug product specifications and applicable fee.**	

Case No. 4: Registration applications for local manufacturing of (Veterinary) drugs. (Differential fee)

a; New cases:

930.	Name and address of manufacturer/ Applicant	M/s Elko Organization (Pvt.) Ltd. Plot No. 27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	CLOMEB Oral Suspension (Vet)
	Composition	Each ml contains: Closantel……...50mg Mebendazole……75mg
	Diary No. Date of R & I & fee	Dy. No.11 dated 03-11-2010, Rs.8000/- dated 02-11-2010 vide Challan No.335/5 dated 12-10-2010 (photocopy) Dy.No. 729 dated 24-06-2013, Differential fee Rs.12000/- dated 24-06-2013 vide Challan No.0006334 dated 13-06-2013 (Photocopy) "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anthelmintics, combinations of Benzimidazoles and related substances.
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2.5 L and 5 L, De-controlled
	Approval status of product in Reference Regulatory Authorities	Supaverm Elanko Animal Health UK AH limited (As provided by the firm)
	Me-too status	Mebentel Oral Drench Each 5ml contains: - Closantel……250mg Mebendazol……375mg M/s Fizi Pharmaceuticals and Chemical laboratories, Raiwind Road, Lahore. Registration No. 081342
	GMP status	Routine GMP inspection conducted on 03-03-2021 by area FID, with conclusion:

		A post-audit meeting was held with the management and their technical staff and all observations pointed out during inspection were discussed at length. The firm assured to address the discussed points as early as possible for attaining a fair level of compliance. Based on above stated observations and keeping in view the attitude of the management towards continuous improvements their current level of compliance is rated as GOOD.
	Remarks of the Evaluator (PEC-XVII)	• Evidence of approval of relevant section is required as the firm has submitted approved layout plan as evidence of availability of Oral Powder General Vet. and Oral Liquid General Vet. Sections. • In routine GMP inspection report dated 03-03-2021, Dry powder (veterinary) & Liquid Syrup (Veterinary) sections are mentioned. • V R & I record verified. Details incorporated in relevant column above.
	Decision: Approved with innovator's specifications. • **Registration board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
931.	Name and address of manufacturer/ Applicant	M/s Elko Organization (Pvt.) Ltd. Plot No. 27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	DE-ZOLE sc 2.5% Oral Suspension (Vet)
	Composition	Each ml contains: Albendazole……...25mg Selenium ……0.27 mg Cobalt……...0.62mg
	Diary No. Date of R & I & fee	Dy.No. 09 dated 03-11-2010, Fee Rs: 8000/- dated 02-11-2010 vide Challan No: 335/4 dated 12-10-2010 (photocopy) Dy.No.729 dated 24-06-2013, Differential fee Rs.12000/- dated 24-06-2013 vide Challan No.0806333 dated 13-06-2013 (Photocopy) "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anthelmintics, ovicidal
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 1L, 2.5: and 5 L, De-controlled
	Approval status of product in Reference Regulatory Authorities	Albenil 2.5% w/v SC Oral Suspension, Virbac animal health, India (As provided by the firm) As per SmPC, the composition is as Each ml contains: Albendazole……25mg, other relevant constituents are; Sodium selenite 0.59mg, eq to 0.27mg Selenium Cobalt sulphate…...2.98mg, eq to 0.63 mg Cobalt.
	Me-too status	ALBENZOL-SC DRENCH. Each ml contains: - Albendazole……50mg Cobalt sulphate…3.82mg Sodium selinite…0.35mg of M/s Selmore, Lahore. Registration No. 035012
	GMP status	Routine GMP inspection conducted on 03-03-2021 by area FID, with conclusion: A post-audit meeting was held with the management and their technical staff and all observations pointed out during inspection were discussed at length. The firm

		assured to address the discussed points as early as possible for attaining a fair level of compliance. Based on above stated observations and keeping in view the attitude of the management towards continuous improvements their current level of compliance is rated as GOOD.
	Remarks of the Evaluator (PEC-XVII)	• Evidence of approval of relevant section is required as the firm has submitted approved layout plan as evidence of availability of Oral Powder General Vet. and Oral Liquid General Vet. Sections. • In routine GMP inspection report dated 03-03-2021, Dry powder (veterinary) and liquid syrup (Veterinay) sections are mentioned. • R & I record verified. Details incorporated in relevant column above. The me-too provided has different composition than the applied formulation. • The reference provided has following composition: Each ml contains Albendazole……25mg, other relevant constituents are; Sodium selenite 0.59mg, eq to 0.27mg Selenium Cobalt sulphate…...2.98mg, eq to 0.63 mg Cobalt.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

Agenda of Evaluator PEC-XVIII

932.	**Name, address of Applicant / Importer**	M/s AMB HK Enterprises (Pvt) Ltd., 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24.02.2023 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Reyoung Pharmaceutical Co., Ltd., No. 1 Ruiyang Road Yiyuan County Shandong Province P.R. China
	Name, address of manufacturer(s)	M/s Reyoung Pharmaceutical Co., Ltd., No. 1 Ruiyang Road Yiyuan County Shandong Province P.R. China
	Name of exporting country	People's Republic of China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP No. 201910002 issued by Yiyuan Market Supervision Administration of P.R China. Validity: 23.10.2021
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted b/w M/s Reyoung Pharmaceutical Co., Ltd., China and M/s AMB HK Enterprises (Pvt) Ltd. Lahore
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 33107 dated 21.10.2021
	Details of fee submitted	PKR /-: 150000/- dated 02.11.2021
	The proposed proprietary name / brand name	**CEFITRIN 1GM INJECTION**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as sodium……1gm
	Pharmaceutical form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	Pack of 1 Vial and 1ampoule of 10ml
	Proposed unit price	Rs. 319.50/- per vail
	The status in reference regulatory authorities	Rocephin 1gm injection
	For generic drugs (me-too status)	Rocephin 1gm Injection (Reg No.050585)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per Module II.
	Name, address of drug substance manufacturer	M/s Reyoung Pharmaceutical Co., Ltd., No. 1 Ruiyang Road Yiyuan County Shandong Province P.R. China
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow diagram of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 30°C ± 2°C / 75 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, method validation studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence data submitted with Rocephin 1gm injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I Glass Vial

		10ml Type I Glass Ampoule
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 36 months Firm requested 36months shelf life
Decision:	**Deferred for following points:** • **Issuance of CoPP by relevant regulatory authority.** • **Submission of legalized CoPP as present expired on 23.10.2021 (2 days after submission of application).**	
933.	Name, address of Applicant / Importer	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi-75700, Pakistan**
	Details of Drug Sale License of importer	**License No:** DHOKW (Drugs)/- **045** **Address:** AGP Limited, B-23-C, S.I.T.E., Karachi-75700, Pakistan. **Address of Godown:** AGP Limited, B-23-C, S.I.T.E., Karachi **Status:** License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter
	Name and address of marketing authorization holder (abroad)	Mylan Laboratories Limited, Plot No. H-12 & H-13, MIDC, Waluj, Aurangabad 431136, Maharashtra state, India
	Name, address of manufacturer(s)	Mylan Laboratories Limited, Plot No. H-12 & H-13, MIDC, Waluj, Aurangabad 431136, Maharashtra state, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. COPP/CERT/AD/80952/2019/11/26583/137729) dated 18-01-2019 issued by Food and Drug Administration Maharashtra State Mumbai for Durart 600 (Darunavir Tablets 600mg). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The CoPP was valid till 17-12-2021** **GMP:** Firm has submitted original, legalized **copy** of GMP certificate (No. NEW-WHO-GMP/CERT/AD/72573/2018/11/26257) dated 20-12-2018 issued by Food and Drug Administration Maharashtra State Mumbai Copy of certificate of GMP compliance by HPRA Ireland based on inspection conducted on 29.11.2019 which can be relied upon to reflect compliance status for three years from date of inspection. **WHO PQ Approval:** Product is prequalified by WHO in 2019. (Reference No. HA685)
	Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from Mylan Laboratories. The letter species that the manufacturer appoints M/s AGP

		Limited to register their products in Pakistan. The authorization letter is valid till 16-Apr-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 28726 dated 20-10-2021
	Details of fee submitted	PKR 75,000/-: 27-09-2021
	The proposed proprietary name / brand name	**DURART 600**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Darunavir Ethanolate equivalent to Darunavir … 600mg
	Pharmaceutical form of applied drug	Film Coated Tablets.
	Pharmacotherapeutic Group of (API)	Anti-retroviral drug (J05AE10)
	Reference to Finished product specifications	In house
	Proposed Pack size	60's (Bottle of 60 Tablets)
	Proposed unit price	As per DRAP Approved Price
	The status in reference regulatory authorities	Darunavir 600mg Tablets **(USFDA** Approved).
	For generic drugs (me-too status)	Not Applicable
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**M/s Mylan Laboratories Limited (Unit-1)** Survey no 10, Gaddapotharam, Kazipally Industrial Area, Sangareddy District – 502319 Telangana State, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API (25516977, 25516978, 25516979) conducted at

		accelerated conditions 40ºC ±2ºC / 75% ± 5% RH for 6 months as well as real time conditions. The real time stability data is conducted at 25ºC ± 2ºC / 60 ± 5% RH & 30ºC ± 2ºC / 75 ± 5% RH. The stability study data is for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted CDP and bioequivalence studies Of Durart 800mg tablet against its innovator brand Prezista® 800mg tablets and bio waiver studies for additional strength Durart 600mg Tablets
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle pack (60's)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (2011139, 2011142, 011144). The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH. The real time stability study data of 3 batches is for 24 months
Decision:	**Approved with Innovator specifications as per Inspection Policy of manufacturers abroad for Finished Drugs.**	
934.	Name, address of Applicant / Importer	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi-75700, Pakistan**
	Details of Drug Sale License of importer	**License No:** DHOKW (Drugs)/- **045** **Address:** AGP Limited, B-23-C, S.I.T.E., Karachi-75700, Pakistan. **Address of Godown:** AGP Ltd**.** B-23-C S.I.T.E 75700, Karachi **Validity:** 21-09-2023. **Status:** License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter.
	Name and address of marketing authorization holder (abroad)	M/s Mylan Laboratories Limited Plot No. H-12 & H-13, MIDC, Waluj, Aurangabad 431136, Maharashtra state, India.
	Name, address of manufacturer(s)	M/s Mylan Laboratories Limited Plot No. H-12 & H-13, MIDC, Waluj, Aurangabad 431136, Maharashtra state, India.
	Name of exporting country	India

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. COPP/CERT/AD/80952/2019/11/26583/137731) dated 18-01-2019 issued by Food and Drug Administration, M.S, Bandra (E), Mumbai Maharashtra state India for Durart 800mg (Darunavir 800mg tablet). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The CoPP was valid till 17-12-2021.** **GMP: GMP:** Firm has submitted original, legalized **copy** of GMP certificate (No. NEW-WHO-GMP/CERT/AD/72573/2018/11/26257) dated 20-12-2018 issued by Food and Drug Administration Maharashtra State Mumbai Copy of certificate of GMP compliance by HPRA Ireland based on inspection conducted on 29.11.2019 which can be relied upon to reflect compliance status for three years from date of inspection. **WHO PQ Approval:** Product is prequalified by WHO in 2019 (Reference Number: HA683)
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Authorization from Mylan Laboratories Ltd. The letter specifies that the manufacturer appoints M/s AGP Ltd. to register their products in Pakistan. The authorization letter is valid till 16-04-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 29006 dated 25-10-2021 Rs.75,000/- dated 27-09-2021
	Details of fee submitted	PKR 75,000/-: 27-09-2021
	The proposed proprietary name / brand name	**DURART 800**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Darunavir Ethanolate equivalent to Darunavir…….800mg
	Pharmaceutical form of applied drug	Film Coated Tablets.
	Pharmacotherapeutic Group of (API)	Antiretroviral drug
	Reference to Finished product specifications	In house

	Proposed Pack size	30's
	Proposed unit price	As per DRAP Approved Price
	The status in reference regulatory authorities	Darunavir 800mg Tablets **(USFDA** Approved).
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Mylan Laboratories Limited (Unit-1) Survey No. 10/42, Gaddapotharam Kazipally Industrial area, Medak district – 502319 Telagana -India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API (25516977, 25516978, 25516979) conducted at accelerated conditions 40^{o}C ±2^{o}C / 75% ± 5% RH for 6 months as well as real time conditions. The real time stability data is conducted at 25^{o}C ± 2^{o}C / 60 ± 5% RH & 30^{o}C ± 2^{o}C / 75 ± 5% RH The stability study data is for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted CDP and bioequivalence studies Of Durart 800mg tablet against its innovator brand Prezista 800mg tablets.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (2011141, 2011143, 2011145) The accelerated stability study data is conducted at 40^{o}C ±2^{o}C / 75% ± 5% RH for 6 months. The long term stability study data is conducted at 30^{o}C ±2^{o}C / 75% ± 5% RH for 24 months.

Decision:	**Approved with Innovator specifications as per Inspection Policy of manufacturers abroad for Finished Drugs.**	
935.	**Name, address of Applicant / Importer**	M/s AMB HK Enterprises (Pvt) Ltd., 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24.02.2023 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Haikou Pharmaceutical Factory Co., Ltd., No. 192 Nanahai Road, Xiuying District Haikou Hainan, China
	Name, address of manufacturer(s)	M/s Haikou Pharmaceutical Factory Co., Ltd., No. 192 Nanahai Road, Xiuying District Haikou Hainan, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (No. Hainan 20200007) issued on 30.04.2020 by Hainan Medical Products Administration, People's Republic of China. **Validity**: 20.12.2020
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted, which indicates agreement of M/s Haikou Pharmaceutical Factory Co., Ltd., & M/s Jilin North Biotech Pharma Imp & Exp Co. Ltd China with M/s AMB HK Enterprises (Pvt) Ltd Lahore
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27485: 05-10-2021
	Details of fee submitted	PKR 100000/- dated 26-04-2021 and 50000/- dated 07-06-2021
	The proposed proprietary name / brand name	**MEROGON INJECTION 1g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as Meropenem trihydrate) …….1g
	Pharmaceutical form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	Pack of 1's Vial

	Proposed unit price	Rs 2463/- per vial
	The status in reference regulatory authorities	**USFDA** Approved.
	For generic drugs (me-too status)	MERONEM Injection of Pfizer (reg no. 096203)
	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Chongqing Tiandi Pharmaceutical Co., Ltd., No. 1 Shenyang Road, Zhongzhou Avenue Zhongxian County Chongquing China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 2-8^{0}C. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been submitted by the manufacturer.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	USP type-I glass
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40^{o}C ±2^{o}C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30^{o}C ±2^{o}C / 75% ± 5% RH. The real time stability study data of 3 batches is for 24 months Firm has also submitted in-use stability data after reconstitution with various diluents used for bolus injection and infusion
Decision: Deferred for submission of valid legalized CoPP as present expired before submission of registration application.		
936.	**Name, address of Applicant / Importer**	M/s AMB HK Enterprises (Pvt) Ltd., 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore

	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24.02.2023 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Haikou Pharmaceutical Factory Co., Ltd., No. 192 Nanahai Road, Xiuying District Haikou Hainan, China
	Name, address of manufacturer(s)	M/s Haikou Pharmaceutical Factory Co., Ltd., No. 192 Nanahai Road, Xiuying District Haikou Hainan, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (No. Hainan 20200006) issued on 30.04.2020 by Hainan Medical Products Administration, People's Republic of China. **Validity**: 20.12.2020
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted, which indicates agreement of M/s Haikou Pharmaceutical Factory Co., Ltd., & M/s Jilin North Biotech Pharma Imp & Exp Co. Ltd China with M/s AMB HK Enterprises (Pvt) Ltd Lahore
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27485: 05-10-2021
	Details of fee submitted	PKR 100000/- dated 26-04-2021 and 50000/- dated 07-06-2021
	The proposed proprietary name / brand name	**MEROGON INJECTION 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as Meropenem trihydrate) …….500mg
	Pharmaceutical form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	Pack of 1's Vial
	Proposed unit price	Rs 1289/- per vial
	The status in reference regulatory authorities	**USFDA** Approved.
	For generic drugs (me-too status)	MERONEM Injection of Pfizer (reg no. 096203)

	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Chongqing Tiandi Pharmaceutical Co., Ltd., No. 1 Shenyang Road, Zhongzhou Avenue Zhongxian County Chongquing China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 2-8^{0}C. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is submitted by the firm
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	USP type-I glass
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40^{o}C ±2^{o}C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30^{o}C ±2^{o}C / 75% ± 5% RH. The real time stability study data of 3 batches is for 24 months Firm has also submitted in-use stability data after reconstitution with various diluents used for bolus injection and infusion
Decision: Deferred for submission of valid legalized CoPP as present expired before submission of registration application.		
937.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd.** **793-D, Block C, Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor

	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3298) issued on 01-June-2020 Government of the People's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 4309 dated 08.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 14.12.2020
	The proposed proprietary name / brand name	Olaparix 50 Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Olaparib INN …..50mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	1x112's in HDPE Bottle
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Lynparza Capsules USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Qingsong Pharmaceutical co., Ltd Suite No. 505 Building No. 2 No. 3377 Kangxin Rd, Pudong New Area Shanghai China 201318
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:

In response to PEC letter dated 13.07.2022 following still requires clarification/ or the response of the firm:

- The firm was requested to clarify that under 3.2.S.1.3 You have submitted that drug substance is white to off white powder and no polymorphic form exists, however the as per innovator data the Olaparib exists as crystalline powder in four polymorphic forms. However, the query was not addressed.
- The firm was requested to clarify that API is characterized by HNMR study only, characterization of the active substance, polymorphic forms/ impurities are required to be performed as per innovator product (3.2.S.3). However, the query was not addressed.
- The firm was requested to clarify that Particle size (being critical quality attribute) and residual solvents are not specified, this requires justification (3.2.S.4).
- The firm was requested to clarify that Drug substance specifications by drug product manufacturer are required (3.2.S.4)) along with results of analysis of relevant batch(es) of Drug Substance performed by drug

product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA).

- Comparative dissolution profile is conducted by Alpha Laboratories Mumbai India instead of manufacturer. In this regard the firm has informed that for more consistency we did comparative dissolution from third part and in future BE study will also be conducted by Alpha Laboratories Mumbai India.
- The firm was requested to clarify that Stability data of Drug Product indicates same test results/ value for the parameters like moisture content, dissolution and assay, hence raw data needs to be submitted for verification However, the query was not addressed

Decision: **Deferred for clarification/ submission of following documents:**

i. **You have submitted that drug substance is white to off white powder and no polymorphic form exists, however the as per innovator data the Olaparib exists as crystalline powder in four polymorphic forms.**

ii. **API is characterized by HNMR study only, characterization of the active substance, polymorphic forms/ impurities are required to be performed as per innovator product.**

iii. **Particle size (being critical quality attribute) and residual solvents are not specified.**

iv. **The firm was requested to clarify that drug substance specifications by drug product manufacturer are required (3.2.S.4)) along with results of analysis of relevant batch(es) of drug substance performed by drug product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA).**

v. **Comparative dissolution profile is conducted by Alpha Laboratories Mumbai India, as the submitted justification is not relevant.**

vi. **Stability data of Drug Product indicates same test results/ value for the parameters like moisture content, dissolution and assay, hence raw data needs to be submitted for verification**

938.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd.** **793-D, Block C, Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3302) issued on 01-June-2020 Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. **GMP:** Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/5027) issued by M/s Beacon Pharmaceuticals limited.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3566 dated 01.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 29.09.2020
	The proposed proprietary name / brand name	Olaparix 150 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Olaparib INN …..150mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	120's in HDPE Bottle
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Lynparza Tablets USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Qingsong Pharmaceutical co., Ltd Suite No. 505 Building No. 2 No. 3377 Kangxin Rd, Pudong New Area Shanghai China 201318
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40^{o}C±2^{o}C and 75%±5% RH for 6 months. Real time stability studies conducted at 30^{o}C±2^{o}C and 65% ± 5% for 24 months

Evaluation by PEC:

In response to PEC letter dated 13.07.2022 following still requires clarification/ or the response of the firm:

- The firm was requested to clarify that under 3.2.S.1.3 You have submitted that drug substance is white to off white powder and no polymorphic form exists, however the as per innovator data the Olaparib exists as crystalline powder in four polymorphic forms. However, the query was not addressed.
- The firm was requested to clarify that API is characterized by HNMR study only, characterization of the active substance, polymorphic forms/ impurities are required to be performed as per innovator product (3.2.S.3). However, the query was not addressed.
- The firm was requested to clarify that Particle size (being critical quality attribute) and residual solvents are not specified, this requires justification (3.2.S.4).
- The firm was requested to clarify that Drug substance specifications by drug product manufacturer are required (3.2.S.4)) along with results of analysis of relevant batch(es) of Drug Substance performed by drug product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture are required.
- Comparative dissolution profile is conducted by Alpha Laboratories Mumbai India instead of manufacturer. In this regard the firm has informed that for more consistency we did comparative dissolution from third part and in future BE study will also be conducted by Alpha Laboratories Mumbai India.
- The firm was requested to clarify that Stability data of Drug Product indicates same test results/ value for the parameters like moisture content, dissolution and assay, hence raw data needs to be submitted for verification However, the query was not addressed Stability data of Drug Product indicates same test results/ value for the parameters like moisture content, dissolution and assay, hence raw data needs to be submitted for verification.

Decision: **Deferred for clarification/ submission of following:**

i. **You have submitted that drug substance is white to off white powder and no polymorphic form exists, however the as per innovator data the Olaparib exists as crystalline powder in four polymorphic forms.**
ii. **API is characterized by HNMR study only, characterization of the active substance, polymorphic forms/ impurities are required to be performed as per innovator product.**
iii. **Particle size (being critical quality attribute) and residual solvents are not specified.**
iv. **The firm was requested to clarify that drug substance specifications by drug product manufacturer are required (3.2.S.4)) along with results of analysis of relevant batch(es) of drug substance performed by drug product manufacturer**

		used during product development and stability studies, along with Certificate of Analysis (CoA). **v. Comparative dissolution profile is conducted by Alpha Laboratories Mumbai India, as the submitted justification is not relevant.** **vi. Stability data of Drug Product indicates same test results/ value for the parameters like moisture content, dissolution and assay, hence raw data needs to be submitted for verification**
939.	**Name, address of Applicant / Importer**	**M/s. Zam Zam Pharmaceutical** Suit#16, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi, Pakistan
	Details of Drug Sale License of importer	**License No: 1205** **Address:** Suit no. 16, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi **Address of Godown:** Al Madina Arcade shop no 5, Clifton Karachi **Validity:** 15-Feb-2022. **Status:** License to sell drugs as distributor **Renewal:** Last Renewal applied on 14th February 2022.
	Name and address of marketing authorization holder (abroad)	Name: **POLIFARMA İLAÇ SAN. VE TIC. A.Ş** Address: Vakıflar OSB Mahallesi, Sanayi Caddesi No:22/1 Ergene Tekirdağ Turkey
	Name, address of manufacturer(s)	Name: **AROMA İLAÇ SAN. LTD. ŞTİ** Address: Vakıflar OSB Mahallesi, Sanayi Caddesi No:22/1 Kat: 2 Ergene Tekirdağ Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2021/128) dated 14-01-2021 issued by Republic of Turkey Ministry of Health Turkish Medicines and Medical Device Agency for OMNIPOL 350 mg/ml solution for I.A, I.V Injection. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 year as per Turkish Ministry of Health regulations. The aforesaid CoPP is valid till 14-01-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from POLIFARMA ILAC S. Ltd in name of M/s Zam Zam Pharmaceutical, Karachi to register and sale applied product in Pakistan. The authorization letter is valid till 14.12.2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27704 dated 06-10-2021
	Details of fee submitted	PKR 150,000/-: 13-07-2021

	The proposed proprietary name / brand name	OMNIPOL 300mgI/ml Solution for I.A., I.V Intrathecal injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: 647 mg of Iohexol equivalent to 300 mg of Iodine
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	X-ray contrast media
	Reference to Finished product specifications	USP
	Proposed Pack size	50& 100ml Vial
	Proposed unit price	50ml, MRP: Rs.2160/- 100ml, MRP: Rs. 3200/-
	The status in reference regulatory authorities	Omnipaque 300mg of USFDA
	For generic drugs (me-too status)	Hoffman Human Health Pakistan Ltd, Iobrix-300 Injection, Reg.no: 032123
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Iohexol is manufactured, tested, released and evaluated on stability by: Zhejiang Starry Pharmaceutical Co., Ltd. (Starry) No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju, Zhejiang, 317300, China (Firm has submitted CEP certificate)
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25ºC ± 2ºC. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence data is submitted with reference product (Omnipaque Injection of GE Healthcare USA)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	OMNİPOL 300 mg /ml Solution For I.A I.V. Intrathecal drug product is packed with colourless 50 mL and 100 mL **Type I** colourless vial covered with 32 mm grey rubber stopper, 32 mm brown aluminium flip tear off cover
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH for 24 months.
Decision:	**Approved with USP specifications as per Inspection Policy of manufacturers abroad for Finished Drugs.**	
940.	Name, address of Applicant / Importer	**M/s. Zam Zam Pharmaceutical** Suit#16, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi, Pakistan
	Details of Drug Sale License of importer	**License No: 1205** **Address:** Suit no. 16, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi **Address of Godown:** Al Madina Arcade shop no 5, Clifton Karachi **Validity:** 15-Feb-2022. **Status:** License to sell drugs as distributor **Renewal:** Last Renewal applied on 14th February 2022.
	Name and address of marketing authorization holder (abroad)	Name: **POLIFARMA İLAÇ SAN. VE TIC. A.Ş** Address: Vakıflar OSB Mahallesi, Sanayi Caddesi No:22/1 Ergene Tekirdağ Turkey
	Name, address of manufacturer(s)	Name: **AROMA İLAÇ SAN. LTD. ŞTİ** Address: Vakıflar OSB Mahallesi, Sanayi Caddesi No:22/1 Kat: 2 Ergene Tekirdağ Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2021/127) dated 14-01-2021 issued by Republic of Turkey Ministry of Health Turkish Medicines and Medical Device Agency for OMNIPOL 350 mg/ml solution for I.A, I.V Injection. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 year as per Turkish Ministry of Health regulations. The aforesaid CoPP is valid till 14-01-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from POLIFARMA ILAC S. Ltd in name of M/s Zam Zam Pharmaceutical, Karachi to register and sale applied product in Pakistan. The authorization letter is valid till 14.12.2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27703 dated 06-10-2021
	Details of fee submitted	PKR 150,000/-: 13-07-2021
	The proposed proprietary name / brand name	Omnipol 350mg/ml Solution for I.A., I.V Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: 755mg of Iohexol equivalent to 350 mg of Iodine
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	X-Ray/ Radiographic contrast media
	Reference to Finished product specifications	USP
	Proposed Pack size	50 ml & 100 ml vial
	Proposed unit price	Packsize:50ml, MRP: Rs.2520/- Pack size:100ml, MRP: Rs. 4680/-
	The status in reference regulatory authorities	Omnipaque 350mg – USA by GE healthcare
	For generic drugs (me-too status)	Hoffman Human Health Pakistan Ltd, Iobrix-350 Injection, Reg.no: 032124
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Iohexol is manufactured, tested, released and evaluated on stability by: Zhejiang Starry Pharmaceutical Co., Ltd. (Starry) No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju, Zhejiang, 317300, China (CEP certificate is submitted for the API)
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ± 2°C. The stability study data is till 36 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence data is submitted with reference product (Omnipaque Injection of GE Healthcare USA)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Sterile solution of OMNİPOL 350 mgI/ml Solution For I.A., I.V. Injection is marketed with closure system which are 50, 100 mL **Type I clear glass vial**, closed with 32 mm grey rubber stopper and sealed with 32 mm green flip tear off cover.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH for 24 months.
Decision:	**Approved with USP specifications as per Inspection Policy of manufacturers abroad for Finished Drugs.**	
941.	**Name, address of Applicant / Importer**	**M/s. Glisten Pharma,** Plot No. 520 Sector 7/A Korangi Industrial Area Karachi.
	Details of Drug Sale License of importer	**License No:** 10930 dated 15.04.2019 **Address:** Plot No. 520 Sector 7/A Korangi Industrial Area Karachi. **Address of Godown:** NA **Validity:** 19.02.2021 **Status:** Drug License by way of Whole Sale
	Name and address of marketing authorization holder (abroad)	M/s Pierrel Pharma S.R.L., Strada Statale Appia 46/48-& Bis 46/48 81043Capua Italy
	Name, address of manufacturer(s)	M/s Pierrel S.p.A Strada Statale Appia 46/48-& Bis 46/48 81043Capua Italy
	Name of exporting country	Italy
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP Bo. No CPP /2019/1312 dated 18.06.2019
	Details of letter of authorization / sole agency agreement	The firm has submitted original sole agency agreement dated 11.09.2019 by marketing authorization holder i.e. M/s Pierrel Pharma S.R.L., Strada Statale Appia 46/48-& Bis 46/48 81043Capua Italy
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27812 dated 07.10.2021
	Details of fee submitted	PKR 100,000/- dated 06.01.2021
	The proposed proprietary name / brand name	ORABLOC 1:100,000
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml solution for injection contains: Articaine HCl….40mg Adrenaline (Epinephrine) as tartrate….0.01mg
	Pharmaceutical form of applied drug	Solution for Injection for dental use
	Pharmacotherapeutic Group of (API)	Local Anaesthetic
	Reference to Finished product specifications	Ph. Eur
	Proposed Pack size	Rs. 7000/- for 50 Cartridges of 1.8ml
	Proposed unit price	Price will be communicated at time of pricing.
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Articaine 4% with Epinephrine 1:100000 of continental Chemical Company Islamabad. Reg. No: 052238
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**ARTICAINE HCL:** **Name of Holder**: Moehs Iberica S.L Cesar MArtinell Brunet No., 12 A Poligono Industrial rubi Sur Apain 08191 Rubi Barcelona **Sites of Production**: Benechim S.P.R.L Rue Rene Magritte, 163 Belgium 7860 Lessines **Name of Holder:** SIEGFRIED EVIONNAZ SA, Route du Simplon 1, 36 Switzerlan-1902 Evuibbaz **Sites of Production**: SIEGFRIED ST. VULBAS SAS Parc Industrial de la plaine de I'Ain France-01150 Saint-Vulbas **Siegfried Evionnaz SA** Route du Simplon 1, 36 Switzerlan-1902 Evuibbaz **ADERNALINE TARTRATE:** **Name of Holder**: CAMBREX PROFARMACO MILANO S.R.L. Via Curiel, 34 Italy-20067 Paullo, Milano **Site of Production: -** CAMBREX PROFARMACO MILANO S.R.L. Via Curiel, 34 Italy-20067 Paullo, Milano

	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ± 2°C. The stability study data is provided till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted the Pharmaceutical equivalence with reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	The Primary container consists of a 1.8ml glass cartridge made of neutral glass type closed with bromobutyl rubber plunger and bromobutyl rubber seal with an aluminium cap.
	Stability study data of drug product, shelf life and storage conditions	Stability testing results of 3 batches of formulation are reported at 25°C RH 60% for 24 months, **30°C / 65%RH for 12 months** and 40°C RH 75% for 6 months. The only impurity detected whose concentration varies with time and temperature is Articaine acid (Hydrolysis products of Articaine) which although reaches maximum concentration of 0.35% after 6 months at 40°C (stressed condition) still remains within the set specification of NMT 0.4% in area with respect to Articaine. Articaine Acid is the main metabolite of Articaine and the concentrations found in the drug product, even at the end of shelf life does not pose any potential heal concern. The formulation is quite stable and remains within specifications after 24 months at 25°C, consequently a shelf life storage condition of 24 months at 25°C is proposed for the drug product stored in its commercial packaging.
Query		**Reply**
i.	Valid Drug Sale License because the submitted copy indicates validity till 19.02.2022.	i. The firm has submitted new drug sale license issued vide No. 0129 No. DHO (East) Drug-786 dated 18.06.2021 valid till 10.06.2023. having address Office No. 403 4th Floor Al Reef Tower, Plot No. 391/3 BYCHS Alamgir Road Karachi. The address mentioned on the aforesaid new DSL is different from the address of the DSL submitted initially with the application.
ii.	Differential fee of 50,000/- is required w.r.t. revised fee SRO because registration application was submitted on 07.10.2021.	ii. The firm has now submitted the differential fee of 50000/- vide Slip No. 17375749 dated 03.08.2022.

iii. Proposed Price needs to be submitted being requirement of application i.e. Form-5F. iv. Reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price as required under 1.5.8. v. Long term stability study data need to be submitted as per Zone IV-A i.e. (30ºC/65%RH).	iii. The firm submitted price of Rs. 7000/- for 50 Cartridges of 1.8ml. iv. Articaine 4% with Epinephrine 1:100000 of continental Chemical Company Islamabad. v. Reg. No: 052238. vi. The firm has attached intermediate study of 30ºC / 65%RH for 12 months of three batches which has already been provided.

Decision: Deferred for following:

- **Clarification whether the sole agency agreement is with M/s. Glisten Pharma, Plot No. 520 Sector 7/A Korangi Industrial Area Karachi or with M/s Glisten Pharma Office No. 403 4th Floor Al Reef Tower, Plot No. 391/3 BYCHS Alamgir Road Karachi.**
- **Clarification of the address of DSL since two DSL with different address have been submitted.**
- **Submission of long term stability studies data as per Zone IV a conditions till claimed shelf life.**

942.	**Name, address of Applicant / Importer**	**M/s. Glisten Pharma,** Plot No. 520 Sector 7/A Korangi Industrial Area Karachi.
	Details of Drug Sale License of importer	**License No:** 10930 dated 15.04.2019 **Address:** Plot No. 520 Sector 7/A Korangi Industrial Area Karachi. **Address of Godown:** NA **Validity:** 19.02.2021 **Status:** Drug License by way of Whole Sale
	Name and address of marketing authorization holder (abroad)	M/s Pierrel Pharma S.R.L., Strada Statale Appia 46/48-& Bis 46/48 81043Capua Italy
	Name, address of manufacturer(s)	M/s Pierrel S.p.A Strada Statale Appia 46/48-& Bis 46/48 81043Capua Italy
	Name of exporting country	Italy
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP Bo. No CPP /2019/1312 dated 18.06.2019
	Details of letter of authorization / sole agency agreement	The firm has submitted original sole agency agreement dated 11.09.2019 by marketing authorization holder i.e. M/s Pierrel Pharma S.R.L., Strada Statale Appia 46/48-& Bis 46/48 81043Capua Italy
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27812 dated 07.10.2021

	Details of fee submitted	PKR 100,000/- dated 06.01.2021
	The proposed proprietary name / brand name	ORABLOC 1:200,000
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml solution for injection contains: Articaine HCl….40mg Adrenaline (Epinephrine) as tartrate….0.005mg
	Pharmaceutical form of applied drug	Solution for Injection for dental use
	Pharmacotherapeutic Group of (API)	Local Anaesthetic
	Reference to Finished product specifications	Ph. Eur
	Proposed Pack size	Rs. 7000/- for 50 Cartridges of 1.8ml
	Proposed unit price	Price will be communicated at time of pricing.
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Articaine 4% with Epinephrine 1:200000 of continental Chemical Company Islamabad. Reg. No: 052239
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**ARTICAINE HCL:** . **Name of Holder**: Moehs Iberica S.L Cesar MArtinell Brunet No., 12 A Poligono Industrial rubi Sur Apain 08191 Rubi Barcelona **Sites of Production**: Benechim S.P.R.L Rue Rene Magritte, 163 Belgium 7860 Lessines . **Name of Holder:** SIEGFRIED EVIONNAZ SA, Route du Simplon 1, 36 Switzerlan-1902 Evuibbaz **Sites of Production**: SIEGFRIED ST. VULBAS SAS Parc Industrial de la plaine de I'Ain France-01150 Saint-Vulbas **Siegfried Evionnaz SA** Route du Simplon 1, 36 Switzerlan-1902 Evuibbaz **ADERNALINE TARTRATE:** **Name of Holder**: CAMBREX PROFARMACO MILANO S.R.L. Via Curiel, 34 Italy-20067 Paullo, Milano **Site of Production:-** CAMBREX PROFARMACO MILANO S.R.L. Via Curiel, 34 Italy-20067 Paullo, Milano
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25ºC ± 2ºC. The stability study data is provided till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted the Pharmaceutical equivalence with reference products.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	The Primary container consists of a 1.8ml glass cartridge made of neutral glass type closed with bromobutyl rubber plunger and bromobutyl rubber seal with an aluminium cap.
	Stability study data of drug product, shelf life and storage conditions	Stability testing results of 3 batches of formulation are reported at 25ºC RH 60% for 24 months, **30ºC / 65%RH for 12 months** and 40ºC RH 75% for 6 months. The only impurity detected whose concentration varies with time and temperature is Articaine acid (Hydrolysis products of Articaine) which although reaches maximum concentration of 0.35% after 6 months at 40ºC (stressed condition) still remains within the set specification of NMT 0.4% in area with respect to Articaine. Articaine Acid is the main metabolite of Articaine and the concentrations found in the drug product, even at the end of shelf life does not pose any potential heal concern. The formulation is quite stable and remains within specifications after 24 months at 25ºC, consequently a shelf life storage condition of 24 months at 25ºC is proposed for the drug product stored in its commercial packaging.
Query		**Reply**
vi.	Valid Drug Sale License because the submitted copy indicates validity till 19.02.2022.	The firm has submitted new drug sale license issued vide No. 0129 No. DHO (East) Drug-786 dated 18.06.2021 valid till 10.06.2023. having address Office No. 403 4th Floor Al Reef Tower, Plot No. 391/3 BYCHS Alamgir Road Karachi. The address mentioned on the aforesaid new DSL is different from the address of the DSL submitted initially with the application.
vii.	Differential fee of 50,000/- is required w.r.t. revised fee SRO because registration application was submitted on 07.10.2021.	The firm has now submitted the differential fee of 50000/- vide Slip No. 17375740 dated 03.08.2022.
viii.	Proposed Price needs to be submitted being requirement of application i.e. Form-5F.	The firm submitted price of Rs. 7000/- for 50 Cartridges of 1.8ml.
ix.	Reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price as required under 1.5.8.	Articaine 4% with Epinephrine 1:100000 of continental Chemical Company Islamabad. Reg. No: 052238.

x.	Long term stability study data need to be submitted as per Zone IV-A i.e. (30ºC/65%RH).	The firm has attached intermediate study of 30ºC / 65%RH for 12 months of three batches which has already been provided.
Decision: Deferred for following: • **Clarification whether the sole agency agreement is with M/s. Glisten Pharma, Plot No. 520 Sector 7/A Korangi Industrial Area Karachi or with M/s Glisten Pharma Office No. 403 4th Floor Al Reef Tower, Plot No. 391/3 BYCHS Alamgir Road Karachi.** • **Clarification of the address of DSL since two DSL withdifferent address have been submitted.** • **Submission of long term stability studies data as per Zone IV a conditions till claimed shelf life.**		
943.	**Name, address of Applicant / Importer**	M/s AMB HK Enterprises (Pvt) Ltd., 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24.02.2023 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Haikou Pharmaceutical Factory Co., Ltd., No. 192 Nanahai Road, Xiuying District Haikou Hainan, China
	Name, address of manufacturer(s)	M/s Haikou Pharmaceutical Factory Co., Ltd., No. 192 Nanahai Road, Xiuying District Haikou Hainan, China
	Name of exporting country	People's Republic of China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (No. Hainan 20210045) issued on 04.03.2021 by Hainan Provincial Medical Products Administration, People's Republic of China. **Validity: 03.03.2023**
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted, which indicates agreement of M/s Haikou Pharmaceutical Factory Co., Ltd., & M/s Jilin North Boitech Pharma Imp & Exp Co. Ltd China with M/s M/s AMB HK Enterprises (Pvt) Ltd Lahore.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27481dated 05.10.2021
	Details of fee submitted	PKR /-: 150000/- dated 07.06.2021
	The proposed proprietary name / brand name	Paclitol Injection

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 16.7ml contains: Paclitaxel…...100mg
	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	USP
	Proposed Pack size	1's Vial (Tube Type Injection Bottle of Low Borosilicate Glass)
	Proposed unit price	Rs. 5150/-
	The status in reference regulatory authorities	USFDA/ MHRA
	For generic drugs (me-too status)	Paclitaxel Ebewe 100mg Injection Reg. No. 083094
	Module-II (Quality Overall Summary)	Firm has submitted not submitted QOS as per WHO QOS-PD template.
	Name, address of drug substance manufacturer	M/s Wuxi Taxus Pharmaceutical Co., Ltd No. 111 Quxin Rd, Donggang Town Xishan Distt., Wuxi China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 30°C ± 2°C / 65 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, method verification studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product of BMS are submitted
	Analytical method validation/verification of product	Firm has not submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	(Tube Type Injection Bottle of Low Borosilicate Glass)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 36 months. Firm requested 36months shelf life.
Decision:	**Approved with USP specifications as per Inspection Policy of manufacturers abroad for Finished Drugs.**	

M/s Evergreen Pharmaceuticals.
69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
DML No. 000786 (Formulation)
Central Licensing Board in its 287th meeting held on 24th June, 2022 has considered and approved the grant of following sections in the name of M/s Evergreen Pharmaceuticals, vide approval letter No. F. 1-31/2010- Lic (Vol-1) dated 4th July, 2022: -

i. Powder injectable penicillin section
ii. Oral powder penicillin section 7 Molecule/10 Products

Powder injectable penicillin section
3 Molecule/3 Products

944.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Provet-5 Injection
	Composition	Each Vial Contains: Benzyl Penicillin…500,000 IU Procaine Penicillin…1,500,000 IU Streptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy. No 6892: 11-03-2022 PKR 30,000/-: 07-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	1's (4gm) vial: Decontrolled
	Me-too status	Penivet-5 (Reg# 008032)
	Remarks of the Evaluator	
	Decision: **Approved**	
945.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Provet forte Injection
	Composition	Each Vial Contains: Penicillin G Procaine…3,000,000 IU Penicillin G Sodium…1,000,000 IU Dihydrostreptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy. No 6898: 11-03-2022 PKR 30,000/-: 07-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	1's (6.5gm) vial: Decontrolled
	Me-too status	Penivet Forte Injection of Star Lab (Reg.# 017945)
	Remarks of the Evaluator	
	Decision: **Approved**	
946.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	E-40 Injection
	Composition	Each Vial Contains: Benzyl Penicillin…1,000,000 IU Procaine Penicillin…3,000,000 IU
	Diary No. Date of R& I & fee	Dy. No 6896: 11-03-2022 PKR 30,000/-: 07-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	1's (3.5gm) vial: Decontrolled
	Me-too status	I-40 Lac Injection of International Pharma (Reg# 074770)
	Remarks of the Evaluator	

	Decision: **Approved**

Oral powder penicillin section 7 Molecule/10 Products		
947.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Tinomox Powder
	Composition	Each 100gm Contains: Amoxicillin Trihydrate…10gm Spectinomycin Hcl…5gm Lincomycin Hcl…5gm
	Diary No. Date of R& I & fee	Dy. No 5218: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	500gm, 1000gm: Decontrolled
	Me-too status	Linco-S Power of Intervac Pvt. Ltd. (Reg#087181)
	Remarks of the Evaluator	Amoxicillin, spectinomycin and lincomycin molecules presentation are not as per reference.
	Decision: **Approved with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
948.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Mycomox Powder
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate Eq. to Amoxicillin…100gm Colistin Sulphate…**50**0 MIU Neomycin Sulphate…200gm
	Diary No. Date of R& I & fee	Dy. No 5216: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Amcocin (Reg. 083243)
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm shall be submitted
	Decision: **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
949.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Calmox Powder
	Composition	Each 1000gm Contains: Amoxicillin as Amoxicillin Trihydrate…160gm Clavulanic Acid as Potassium Clavulanate…40gm Bromhexine Hcl…5gm
	Diary No. Date of R& I & fee	Dy. No 5212: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled

	Me-too status	Clavexine Powder of Baariq Pharma (Reg#087172)
	Remarks of the Evaluator	Amoxicillin & Clavulanic Acid molecule presentation is not as per reference.
	Decision: **Approved with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
950.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Comovit Oral Powder
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate Eq. to Amoxicillin…200gm Spectinomycin Sulphate Eq. to Spectinomycin…88gm Lincomycin Hcl Eq. to Lincomycin…88gm Vitamin-E Acetate…30gm
	Diary No. Date of R& I & fee	Dy. No 5213: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Lincomoxel Plus oral Powder (Reg 080960)
	Remarks of the Evaluator	
	Decision: **Approved**	
951.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Colimox Powder
	Composition	Each 100gm Contains: Amoxicillin as Trihydrate…20gm Colistin as Sulphate…50,000,000 IU
	Diary No. Date of R& I & fee	Dy. No 5214: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	100gm, 200gm,400gm, 500gm, 1000gm: Decontrolled
	Me-too status	Amoxy-co Powder (Reg 046641)
	Remarks of the Evaluator	
	Decision: **Approved**	
952.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Moxicol W/S Powder
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate…200gm Colistin Sulphate…800 IU
	Diary No. Date of R& I & fee	Dy. No 5215: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	500gm, 1000gm: Decontrolled
	Me-too status	Moxabect w/s Powder (Reg#088642)
	Remarks of the Evaluator	Amoxicillin molecule presentation is not as per reference
	Decision: **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

953.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Oxitin Powder
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate…150gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy. No 5210: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Amoxycol Powder (Reg# 043269)
	Remarks of the Evaluator	Amoxicillin molecule presentation is not as per reference
	Decision: **Approved with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
954.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	G-Mox Powder
	Composition	Each gm Contains: Amoxicillin as Trihydrate…160mg Clavulanic Acid as Potassium Clavulanate…40mg
	Diary No. Date of R& I & fee	Dy. No 5212: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Clavet Powder (Reg.#034582)
	Remarks of the Evaluator	
	Decision: **Approved**	
955.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	SP-Mox-50 Powder
	Composition	Each gm Contains: Amoxicillin Trihydrate Eq. to Amoxicillin…500mg
	Diary No. Date of R& I & fee	Dy. No 5209: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	BP specification
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Amosel-50 Powder (Reg.#080959)
	Remarks of the Evaluator	
	Decision: **Approved**	
956.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	SP-Mox-70 Powder
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate 800gm Eq. to Amoxicillin…700gm
	Diary No. Date of R& I & fee	Dy. No 5211: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic

	Type of Form	Form-5
	Finished Product Specification	BP specification
	Pack size & Demanded Price	500gm, 1000gm: Decontrolled
	Me-too status	Reg. 074032) PRIMOX 70% WATER SOLUBLE POWDER
	Remarks of the Evaluator	
	Decision: **Approved**	

M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan DML No. 000949 (New Licence)

Central Licensing Board in its 284th meeting held on 16th December, 2021 has considered and approved the grant of Drug Manufacturing Licence by way of Formulation, vide approval letter No. F. 1-17/2016- Lic dated 22nd December, 2021 with following four (04) sections: -

1. Oral Powder (General) Section (Veterinary)
2. Oral Liquid (General) Section (Veterinary)
3. Oral Powder (Penicillin) Section (Veterinary)
4. Liquid Injection (Penicillin) Section (Veterinary)

Oral Liquid (General) Section (Veterinary)
11 Molecules/12 Products

957.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Parazole Oral Liquid**
	Composition	Each 1000ml Contains: Albendazole…100gm
	Diary No. Date of R& I & fee	Dy No: 10018, Dated:20-04-2022, Rs. 30,000/- Dated:18-03-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Albacon-10% Liquid Suspension by M/s Vetcon Pharmaceuticals Pvt. Ltd (Reg#31505)
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
958.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. 1 Km Off, 16 Km Sargodha Road, Mangowal West District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Med Oxfen Oral Liquid
	Composition	Each ml Contains: Oxfendazole…22.65mg
	Diary No. Date of R& I & fee	Dy. No 12284: 20-05-2022 PKR 30,000/-: 12-05-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	USP specification
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Oxfendacon Oral Liquid (Reg# 031500)
	Remarks of the Evaluator	
	Decision: Approved	
959.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Flore Med 23 Oral Liquid**
	Composition	Each ml Contains: Florfenicol…230mg

	Diary No. Date of R& I & fee	Dy No:10021, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Baflor-23 Oral Solution by M/s Baariq Pharmaceuticals (Reg#071096)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
960.	Name and address of manufacturer/ Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Oxy Cob Oral Liquid**
	Composition	Each ml Contains: Oxyclozanide…62.5mg Oxfendazole…22.65mg Sodium Selenite…0.5mg Cobalt Sulphate…1.67mg
	Diary No. Date of R& I & fee	Dy No:10023, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Oxfendaox Plus Oral Drench by M/s Baariq Pharmaceuticals (Reg#075786)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
961.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Leva Cos Plus Oral Liquid**
	Composition	Each ml contains: - Levamisole HCl …15mg Cobalt sulphate …1.67mg Oxyclozanide …30mg Sodium selenite …0.50mg
	Diary No. Date of R& I & fee	Dy No:10036, Dated:20-04-2022, Rs. 30,000, Dated:29-03-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Levoxbar-Plus Drench by M/s Baariq Pharmaceuticals (Reg#075788)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
962.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Floridon Oral Liquid**

	Composition	Each 1000ml Contains: Florfenicol…100gm
	Diary No. Date of R& I & fee	Dy No:10037, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Maxi-Flor Liquid by M/s Biogen Pharma (Reg#075612)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
963.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Trimo Chick Oral Liquid**
	Composition	Each 1000ml Contains: Sulphadiazene…400gm Trimethoprim…80gm
	Diary No. Date of R& I & fee	Dy No:10032, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Timobar Suspension by M/s Baariq Pharmaceuticals (Reg#079817)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
964.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Med TS Oral Liquid**
	Composition	Each 1000ml Contains: Enrofloxacin…75gm Sulphamethoxypyridazine…75gm Sulphamerazine …50gm Trimethoprim…25gm
	Diary No. Date of R& I & fee	Dy No:10033, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Cina T.S Oral Suspension by M/s Vety-Care Pharmaceutical (Pvt) Ltd (Reg#031456)
	Remarks of the Evaluator	Me-too is not same
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
965.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Compli Med Oral Liquid**
	Composition	Each 1000ml Contains: Tylosin Tartrate…50gm

		Sulphamethoxypyridazine…50gm Trimethoprim…10gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy No:10034, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Compli-Plus Liquid by M/s Elegance Pharmaceuticals (Reg#073998)
	Remarks of the Evaluator	Submitted me-too reference (Reg#073998) contains Sulphamethoxypyridazine Sodium, whereas, applied formulation has Sulphamethoxypyridazine base.
	Decision: Approved with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
966.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Medi Flu Oral Liquid**
	Composition	Each 1000ml Contains: Enrofloxacin…100gm Colistin Sulphate…800 MIU
	Diary No. Date of R& I & fee	Dy No:10035, Dated:20-04-2022, Rs. 30,000, Dated:29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	078292 (Doesn't match with applied formulation)
	Remarks of the Evaluator	i. Firm revised formulation without fee Each 1000ml Contains: Enrofloxacin…100gm Colistin Sulphate…500 MIU
	Decision: Approved with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
967.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. 1 Km Off, 16 Km Sargodha Road, Mangowal West District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Anthel Med Oral Liquid
	Composition	Each 1000ml Contains: Albendazole…100gm Ivermectin…2gm Triclabendazole…120gm
	Diary No. Date of R& I & fee	Dy. No 12280: 20-05-2022 PKR 30,000/-: 12-05-2022
	Pharmacological Group	**anthelminthic**
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Thunder Drench (Reg# 058941)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

968.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. 1 Km Off, 16 Km Sargodha Road, Mangowal West District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Iver Med Oral Liquid
	Composition	Each ml Contains: Ivermectin…2mg
	Diary No. Date of R& I & fee	Dy. No 12282: 20-05-2022 PKR 30,000/-: 12-05-2022
	Pharmacological Group	**anthelminthic**
	Type of Form	Form-5
	Finished Product Specification	BP specification
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	(Reg# 019057) IVOSOL 0.2% DRENCH
	Remarks of the Evaluator	
	Decision: Approved	
Liquid Injection (Penicillin) Section (Veterinary) 8 Molecules/9 Products		
969.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. 1 Km Off, 16 Km Sargodha Road, Mangowal West District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Medpiclox Injection
	Composition	Each ml Contains: Ampicillin as Trihydrate…125mg Cloxacillin Base…125mg
	Diary No. Date of R& I & fee	Dy. No 12281: 20-05-2022 PKR 30,000/-: 12-05-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	BP specification
	Pack size & Demanded Price	50ml,100ml: Decontrolled
	Me-too status	Ampicox Liquid Injection (Reg#035061)
	Remarks of the Evaluator	
	Decision: Approved	
970.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Flu-Med Liquid Injectable**
	Composition	Each ml Contains: Ceftiofur HCl…50mg
	Diary No. Date of R& I & fee	Dy No:10019, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	**50ml, 100ml**/ Decontrolled
	Me-too status (with strength and dosage form)	Cefur-Rtu Injection by M/s Nawan Laboratories (Pvt) Ltd (Reg#049605)
	Remarks of the Evaluator	• Submitted Me-too formulation has composition: Each ml contains: - Ceftiofur (**as** hydrochloride) 50mg. • Firm has submitted 2 volumes i.e. 50ml and 100ml in the same application dossier.
	Decision: Approved 50ml with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
971.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Mox-Med Liquid Injection**
	Composition	Each ml Contains:

		Amoxicillin (as trihydrate) …150mg
	Diary No. Date of R& I & fee	Dy No:10024, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	**50ml, 100ml**/ Decontrolled
	Me-too status (with strength and dosage form)	Triamoxyl 15% LA Injection by M/s Leads Pharma (Pvt) Ltd (Reg#034593)
	Remarks of the Evaluator	• Firm has submitted 2 volumes i.e. 50ml and 100ml in the same application dossier.
	Decision: Approved 50ml with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
972.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Mox-Vet Injection**
	Composition	Each ml Contains: Amoxicillin (as trihydrate) …100mg Colistin Sulphate…250,000 IU
	Diary No. Date of R& I & fee	Dy No:10027, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	**50ml, 100ml**/ Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Colimoxin Injection by M/s Selmore Pharmaceuticals (Pvt) Ltd. (Reg#034576)
	GMP status	05-11-2021 Panel inspection for grant of DML Panel recommended grant of DML
	Remarks of the Evaluator	• Firm has submitted 2 volumes i.e. 50ml and 100ml in the same application dossier.
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
973.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Amoxogent Injection**
	Composition	Each ml Contains: Amoxicillin Trihydrate…50mg Gentamycin Sulphate…25mg
	Diary No. Date of R& I & fee	Dy No:10030, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	**50ml, 100ml**/ Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Gentacillin Injection by M/s Baariq PharmaceuticalS (Reg#087163)
	GMP status	05-11-2021 Panel inspection for grant of DML Panel recommended grant of DML.

	Remarks of the Evaluator	• Submitted Me-too formulation has composition: Each ml contains:- Gentamicin sulphate **eq. to** Gentamicin …25mg Amoxicillin trihydrate **eq. to** Amoxicillin …50mg • Firm has submitted 2 volumes i.e. 50ml and 100ml in the same application dossier.
	Decision: Approved 50ml with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
974.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Pro Dipen Injection**
	Composition	Each ml Contains: Benzathine Penicillin…100,000 IU Procaine Penicillin…150,000 IU Dihydrostreptomycin Sulphate…200mg
	Diary No. Date of R& I & fee	Dy No:10031, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	**50ml, 100ml**/ Decontrolled
	Me-too status (with strength and dosage form)	Bps-LA Injection **(50ml)** by M/s Selmore Pharmaceuticals (Pvt) Limited (Reg#080951)
	Remarks of the Evaluator	• Submitted Me-too formulation has composition: Each ml contains:- Benzathine penicillin G …100,000 IU Procaine penicillin G …150,000 IU Dihydrostreptomycin sulphate **eq. to** Dihydrostreptomycin …200mg
	Decision: Approved 50ml with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
975.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. 1 Km Off, 16 Km Sargodha Road, Mangowal West District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Medoxyclave Injection
	Composition	Each ml Contains: Amoxicillin as Trihydrate…140mg Clavulanic Acid as Potassium Clavulanate…35mg
	Diary No. Date of R& I & fee	Dy. No 12283: 20-05-2022 PKR 30,000/-: 12-05-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	Me-too status	Clavet Injection (Reg# 046519)
	Remarks of the Evaluator	
	Decision: Approved 50ml with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
976.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. 1 Km Off, 16 Km Sargodha Road, Mangowal West District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Medoxicillin-20 Injection
	Composition	Each ml Contains: Amoxicillin as Trihydrate…200mg

	Diary No. Date of R& I & fee	Dy. No 12285: 20-05-2022 PKR 30,000/-: 12-05-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP specification
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	Me-too status	Primox 20LA Injection (Reg# 102127)
	Remarks of the Evaluator	
	Decision: Approved 50ml	
977.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. 1 Km Off, 16 Km Sargodha Road, Mangowal West District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Ampi Med-20 Injection
	Composition	Each ml Contains: Ampicillin as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy. No 12286: 20-05-2022 PKR 30,000/-: 12-05-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP specification
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	Me-too status	Bio-Ampet 20% Injection (Reg# 088842)
	Remarks of the Evaluator	
	Decision: Approved 50ml	
Oral Dry Powder (General) Section (Veterinary) 10 Molecules/10 Products		
978.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Macrodox N Oral Powder**
	Composition	Each 1000gm Contains: Neomycin Sulphate…720gm
	Diary No. Date of R& I & fee	Dy No:10028, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Nemobar-72 Water Soluble Powder by M/s Baariq Pharmaceuticals (Reg#071100)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
979.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**CTD Bromo Oral Powder**
	Composition	Each 1000gm Contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colistin Sulphate…500 MIU Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy No:10029, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic & mucolytic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled

	Me-too status (with strength and dosage form)	Tycobar-D Water Soluble Powder by M/s Baariq Pharmaceuticals (Reg#071099)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
980.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Med Coc Oral Powder**
	Composition	Each 1000gm Contains: Sulfamerazine…100gm Sulfadiazene…60gm Sulfathiazole…40gm Trimethoprim…40gm
	Diary No. Date of R& I & fee	Dy No:10038, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic & anticoccidial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	TS-30 Powder by M/s Elegance Pharmaceuticals (Reg#074002)
	Remarks of the Evaluator	
	Decision: Referred to EWG on veterinary drugs	
981.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Med Erythro Plus Oral Powder**
	Composition	Each 1000gm Contains: Tylosin Tartrate…60gm Erythromycin Thiocyanate…40gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy No:10040, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic & mucolytic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Tylovit E.F Plus Powder by M/s Leads Pharma (Pvt) Ltd (Reg#044963) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
982.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Quinodine C Oral Powder**
	Composition	Each 1000gm Contains: Enrofloxacin…120gm Colistin Sulphate…500 MIU **Amantadine Hcl**…50gm
	Diary No. Date of R& I & fee	Dy No:10041, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled

	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Colabex Powder by M/s Elegance Pharmaceutical (Reg#073924) (Not same as applied formulation)
	GMP status	05-11-2021 Panel inspection for grant of DML Panel recommended grant of DML.
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database. • Amantadine combination. • Composition in covering letter and form-5 is not same.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
983.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Linco Med Oral Powder**
	Composition	Each 1000gm Contains: Lincomycin HCl…44gm
	Diary No. Date of R& I & fee	Dy No:10042, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Lincomix 44 Premix Powder by M/s Upjhon Pakistan (Pvt) Ltd (Reg#017935)
	Remarks of the Evaluator	Lincomycin as HCL
	Decision: Approved with Innovator specifications. Firm shall submit the full fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
984.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Paradox Oral Powder**
	Composition	Each 1000gm Contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colistin Sulphate…500 MIU **Aminophylline HCl…100gm** Paracetamol…100gm
	Diary No. Date of R& I & fee	Dy No:10047, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic, mucolytic & antipyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	**Not submitted**
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
985.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Fura Med Oral Powder**
	Composition	Each 1000gm Contains:

		Furazolidone…244gm
	Diary No. Date of R& I & fee	Dy No:10049, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Furazone-M Feed Supplement Powder by M/s Manhattan Pharma (Reg#014574)
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
986.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Phenyl Dox Oral Powder**
	Composition	Each 1000gm Contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colistin Sulphate…500 MIU **Phenyl Butazone**…12gm
	Diary No. Date of R& I & fee	Dy No:10046, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Broncodox Water Soluble Powder by M/s Westmont Pharmaceutical Industries (Reg#048203) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
987.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Fosfomox Oral Powder**
	Composition	Each 1000gm Contains: Calcium Fosfomycin…200gm Tylosin Tartrate…100gm Fructose…180gm Sodium Phosphate…150gm Magnesium Phosphate…100gm
	Diary No. Date of R& I & fee	Dy No:10044, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic & minerals
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Fofact Powder by M/s Univet Pharmaceuticals (Reg#075626) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
Oral Dry Powder (Penicillin) Section (Veterinary) 7 Molecules/ 8 Products		

988.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Poul Mix Oral Powder**
	Composition	Each 1000gm Contains: Streptomycin Sulphate…36gm Procaine Penicillin…12gm Zinc Bacitracin…52gm
	Diary No. Date of R& I & fee	Dy No:10020, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled
	Me-too status (with strength and dosage form)	Procabact Powder by M/s Grand Pharma (Pvt) Ltd (Reg#106630)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
989.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Splino Mox Oral Powder**
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate…200gm Lincomycin HCl…88gm Spectinomycin 2Hcl…88gm
	Diary No. Date of R& I & fee	Dy No:10022, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled
	Me-too status (with strength and dosage form)	Harry-Speclin 200 Water Soluble Powder by M/s Haarolds Pharmaceuticals (Pvt) Ltd (Reg#109164) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
990.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Am Col Oral Powder**
	Composition	Each 1000gm Contains: Amoxicillin (as trihydrate) …200gm Colistin Sulphate…800 MIU
	Diary No. Date of R& I & fee	Dy No:10025, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled
	Me-too status (with strength and dosage form)	Moxicot-100 Water Soluble Powder by M/s Grand Pharma (Pvt) Ltd (Reg#102073)
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
991.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Med Mix N Oral Powder**
	Composition	Each 1000gm Contains: Neomycin Sulphate…10gm Streptomycin Sulphate…36gm Procaine Penicillin…12gm Zinc Bacitracin…52gm
	Diary No. Date of R& I & fee	Dy No:10039, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled
	Me-too status (with strength and dosage form)	Flemibiotic Powder by M/s Grand Pharma (Pvt) Ltd (Reg#103942)
	Remarks of the Evaluator	
	Decision: Refer to EWG on veterinary drugs	
992.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Medlimox B Oral Powder**
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate…100gm Lincomycin HCl…50gm Colistin Sulphate…26.3gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy No:10048, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic & mucolytic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg/ Decontrolled
	Me-too status (with strength and dosage form)	Tycobar-D Water Soluble Powder by M/s Baariq Pharmaceuticals (Reg#071099) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
993.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Pro Medcin Oral Powder**
	Composition	Each 1000gm Contains: Streptomycin Sulphate…36gm Procaine Penicillin…12gm Zinc Bacitracin…52gm Sodium Selenite…0.5mg
	Diary No. Date of R& I & fee	Dy No:10045, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled

	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Procabact Powder by M/s Grand Pharma (Pvt) Ltd (Reg#106630) (Not same as applied formulation)
	GMP status	05-11-2021 Panel inspection for grant of DML Panel recommended grant of DML.
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
994.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Med Exel Oral Powder**
	Composition	Each 1000gm Contains: Neomycin Sulphate…10gm Streptomycin Sulphate…36gm Procaine Penicillin…12gm Zinc Bacitracin…52gm Colistin Sulphate…500,000 IU
	Diary No. Date of R& I & fee	Dy No:10043, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled
	Me-too status (with strength and dosage form)	Flemibiotic Powder by M/s Grand Pharma (Pvt) Ltd (Reg#103942) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
995.	Name and address of manufacturer / Applicant	M/s Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Amoxy Poul Oral Powder**
	Composition	Each 1000gm Contains: Amoxicillin (as trihydrate)…200gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy No:10050, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled
	Me-too status (with strength and dosage form)	Skymox Oral Powder by M/s Farm Aid Group (Pvt) Ltd (Reg#087193)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

M/s Selmore Pharmaceuticals, 36-KM Multan Road, Lahore

The CLB in its 287th meeting held on 24th June, 2022 has considered and approved the grant of following six (06) additional sections of firm M/s Selmore Pharmaceuticals, 36-KM Multan Road, Lahore, (DML No.000507) by way of formulation vide approval letter No. F. 1-13/2000-Lic (Vol-II) dated 4th July, 2022, as under:-

1. Liquid Injectable Cephalosporin (Veterinary)
2. Dry Powder Injectable Cephalosporin (Veterinary)
3. Liquid Injectable Vial-I General (Veterinary) **Revised**
4. Liquid Injectable Vial-II General (Veterinary)
5. External Liquid preparation (Veterinary)
6. External Powder Preparation (Veterinary)

Liquid Injection (Cephalosporin) 13 Products / 9 Molecules		
996.	Name and address of manufacturer / Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Cefanome Injection 50ml.
	Composition	Each ml contains: Cefquinome sulphate equivalent to Cefquinome…… 25mg
	Diary No. Date of R& I & fee	Rs.30,000/- & (20984/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Me-too status	COBACTAN Injection, Registration No: 078219. by ICI Pakistan, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator	
	Decision: **Approved**	
997.	Name and address of manufacturer / Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Cefanome Injection 100ml
	Composition	Each ml contains: Cefquinome sulphate equivalent to Cefquinome…… 25mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20985/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	100ml / Decontrolled
	Me-too status	COBACTAN Injection. Registration No: 078219. by ICI Pakistan, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Approved	
998.	Name and address of manufacturer / Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Redycef RTU Injection 10ml.
	Composition	Each ml contains: Ceftiofur as hydrochloride…… 50mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20986/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	10ml / Decontrolled
	Me-too status	CEFUR-RTU Injection, Registration No: 049605.

		by M/s. Nawan Laboratories Pvt. Ltd. Karachi, Pakistan
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Me-too granted 50,100ml
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
999.	Name and address of manufacturer / Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Redycef RTU Injection 50ml.
	Composition	Each ml contains: Ceftiofur as hydrochloride…… 50mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20987/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Me-too status	CEFUR-RTU Injection, Registration No: 049605. by M/s. Nawan Laboratories Pvt. Ltd
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved**	
1000.	Name and address of manufacturer / Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Redycef RTU Injection 100ml.
	Composition	Each ml contains: Ceftiofur as hydrochloride…… 50mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20988/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	100ml / Decontrolled
	Me-too status	CEFUR-RTU Injection, Registration No: 049605. by M/s. Nawan Laboratories Pvt. Ltd. Karachi, Pakistan
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved**	
1001.	Name and address of manufacturer / Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	CEFAPEN INJECTION 50ml.
	Composition	Each ml contains : Cephalexin Monohydrate 157.8mg. equivalent to Cephalexin 150mg.
	Diary No. Date of R& I & fee	Rs.30,000/- (20989/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Me-too status	Cephalexine 15% Injection, Registration No: 085727.by M/s. Mustafa Brothers Faisalabad.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Me-too granted 50ml
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

1002.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	CEFAPEN INJECTION 100ml.
	Composition	Each ml contains : Cephalexin Monohydrate 157.8mg equivalent to Cephalexin 150mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20990/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	100ml / Decontrolled
	Me-too status	Cephalexine 15% Injection, Registration No: 085727, by M/s Mustafa Brothers Faisalabad
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved**	
1003.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Cefagent-AD LC Intramammary Suspension.
	Composition	Each 10ml contains: Cephalexin Monohydrate (Base)….200mg Gentamicin Sulphate (Base)…....100mg Dexamethasone-21 phosphate…….0.75 Mg Vitamin A……..10,000 IU
	Diary No. Date of R& I & fee	Rs.30,000/- (20991/26.07.2022)
	Pharmacological Group	Antibiotic-Anti-inflammatory combination
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	48 Injectors of 10ml / Decontrolled
	Me-too status	CEFA MILK FORTE Intramammary Suspension Registration No: 053955, by M/s Mustafa Brothers Faisalabad
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Cephalexin and Gentamicin salt form presentation is not as per reference
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections.	
1004.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Uteprim Intrauterine Suspension
	Composition	Each 19gm syringe contains: Cephapirin as benzathine……..500mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20992/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specs.
	Pack size & Demanded Price	10 Injectors of 19 gm / Decontrolled
	Me-too status	METRICURE Intrauterine Suspension Registration No: 078355.by ICI Pakistan, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	

	Decision: Deferred for ecidence of availability of manufacturing facility for Intra mammary injections.	
1005.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Cefagent LC Intramammary Suspension
	Composition	Each 10ml syringe contains: Cefalexin as monohydrate…….350mg Gentamicin as sulphate……35mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20993/26.07.2022)
	Pharmacological Group	Antibiotic Combination.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	24 Injectors Of 10ml / Decontrolled
	Me-too status	MASTILEX Intramammary Suspension Registration No: 019980. by M/s VETARIA Pharmaceuticals, Lahore
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for ecidence of availability of manufacturing facility for Intra mammary injections.	
1006.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Cepramast DC Intramammary Suspension
	Composition	Each 3gm syringe contains: Cefalonium…….250mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20994/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic.
	Type of Form	Form-5
	Finished product Specification	(BP-vet Specs.)
	Pack size & Demanded Price	24 Injector Of 3mg / Decontrolled
	Me-too status	CEPRAVIN Intramammary Suspension Registration No: 020133 by ICI Pakistan, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Reference presentation: Cefalonium 250 mg (as cefalonium dihydrate)
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections.	
1007.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Redycef LC Intramammary Suspension
	Composition	Each 10 ml syringe contains: Ceftiofur as Hydrochloride…… 125mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20995/26.07.2022)
	Pharmacological Group	Broad-spectrum Cephalosporin antibiotic.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	12 Injectors of 10ml / Decontrolled
	Me-too status	SPECTRA MAST LC Intramammary Suspension Registration No: 088652.by M/s GHAZI BROTHERS, Karachi

	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections.	
1008.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Redycef DC Intramammary Suspension
	Composition	Each 8 ml syringe contains: Ceftiofur as Hydrochloride…… 500mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20996/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	5 Injectors of 8ml / Decontrolled
	Me-too status	CEFENT DC Intramammary Suspension Registration No: 093830. by M/s UM Enterprises, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections.	
	Dry Powder Injection (Cephalosporin) 2 Products/1 Molecule	
1009.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Ceftisel Dry Powder Injection 1gm
	Composition	Each vial contains : Ceftiofur sodium equivalent to Ceftiofur …… 1g
	Diary No. Date of R& I & fee	Rs.30,000/- (20980/26.07.2022)
	Pharmacological Group	Broad-spectrum Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	1gm Injection
	Me-too status	BRICS Injection, Registration No: 029656 by M/s. Elco Organization (Pvt.) Ltd. Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1010.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Ceftisel Dry Powder Injection 4gm
	Composition	Each vial contains : Ceftiofur sodium equivalent to Ceftiofur …… 4g
	Diary No. Date of R& I & fee	Rs.30,000/- (20981/26.07.2022)
	Pharmacological Group	Broad-spectrum Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	4gm Injection
	Me-too status	ACCENT Injection, Registration No: 026548. by M/s. Ghazi Brothers, Karachi

	GMP status	New Section Approval granted on 04-07-2022
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
Liquid Injectable Vial-I General 2 Products / 1 Molecules		
1011.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	PSEL (Sterile Water For Injection) 20ml (BP Specs)
	Composition	Each vial contains: Sterile Water for Injection (as diluent) ….20ml
	Diary No. Date of R& I & fee	Rs.30,000/- (20982/26.07.2022)
	Pharmacological Group	Diluent/Solvent for Reconstitution
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	20 ml / Decontrolled
	Me-too status	PSOL (Sterile Water for Injection) Registration No: 090136.by M/s Pharmasol Pvt Ltd Lahore, Pakistan.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Submitted me-too of Human drug You have mentioned B.P and USP in specification, mention desired one
	Decision: **Approved**	
1012.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	PSEL (Sterile Water For Injection) 80ml
	Composition	Each vial contains: Sterile Water for Injection (as diluent) … 80ml
	Diary No. Date of R& I & fee	Rs.30,000/- (20983/26.07.2022)
	Pharmacological Group	Diluent/Solvent for Reconstitution
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	80 ml / Decontrolled
	Me-too status	PSOL (Sterile Water for Injection) Registration No: 090136. by M/s Pharmasol Pvt Ltd Lahore, Pakistan.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Submitted me-too of Human drug You have mentioned B.P and USP in specification, mention desired one
	Decision: Deferred for details of the drug product for which applied formulation will be used as diluent.	
External Liquid Preparation 9 Products / 6 Molecules		
1013.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	ECTORIN-10 SOLUTION.
	Composition	Each ml contains: Cypermethrin……..100mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20997/26.07.2022)
	Pharmacological Group	Insecticide
	Type of Form	Form-5
	Finished product Specification	Innovators Specification

	Pack size & Demanded Price	100ml, 250ml ,500ml, 1 litre ,2.5litre / Decontrolled
	Me-too status	CYPERCENT POUR ON SOLUTION Registration No: 079835 by M/s DECENT PHARMA ISLAMABAD.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1014.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	ECTORIN POUR-ON SOLUTION.
	Composition	Each ml contains: Cypermethrin……..200mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20998/26.07.2022)
	Pharmacological Group	Insecticide
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	100ml, 250ml , 500ml, 1 litre / Decontrolled
	Me-too status	ECTOLFEECE-200 LIQUID, Registration No: 063805 by M/s Biogen Pharma Rawat
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1015.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	DIOX 15% SOLUTION.
	Composition	Each ml contains: Diazinon……..150mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20999/26.07.2022)
	Pharmacological Group	External Liquid Preparation (Insecticide)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	250ml,500ml,1 litre,5litre / Decontrolled
	Me-too status	DIPSOL 15% SOLUTION Registration No: 026501, by M/s STAR LABORATORIES, Lahore
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1016.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	DIOX 60% SOLUTION.
	Composition	Each ml contains: Diazinon……..600mg
	Diary No. Date of R& I & fee	Rs.30,000/- (21000/26.07.2022)
	Pharmacological Group	External Liquid Preparation (Insecticide)

	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	250ml, 500ml, 1 litre, 5 litre / Decontrolled
	Me-too status	DIPSOL 60% SOLUTION. Registration No: 026502 by M/s STAR LABORATORIES, Lahore.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1017.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	PROSEL SPRAY.
	Composition	Each 100ml contains: Fipronil……..0.25% w/v
	Diary No. Date of R& I & fee	Rs.30,000/- (21001/26.07.2022)
	Pharmacological Group	insecticides
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	100ml, 250ml , 500ml / Decontrolled
	Me-too status	FRONTLINE SPRAY. Registration No: 02217 by M/s SAADAT INTERNATIONAL, Lahore
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1018.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	PEROXEL Solution.
	Composition	Stabilized Hydrogen Peroxide…. (50% w/w)
	Diary No. Date of R& I & fee	Rs.30,000/- (21002/26.07.2022)
	Pharmacological Group	External Liquid Preparation(Antiseptic)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	1litre, 4 litre, 10 litre, 20 litre / Decontrolled
	Me-too status	AQUA CLEAN Solution. Registration No: 021449 by M/s GHAZI BROTHERS, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Correct specification as topical available in USP
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1019.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	BENZOX Solution.

	Composition	Each litre contains: Benzalkonium chloride…… 400g
	Diary No. Date of R& I & fee	Rs.30,000/- (21003/26.07.2022)
	Pharmacological Group	**Antiseptic and germicides**
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	1 litre, 2.5 litre, 5 litre. / Decontrolled
	Me-too status	BELORAN Solution. Registration No: 026467, by M/s HILTON PHARMA, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Correct specification as topical available in USP Generic not same as applied product.
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1020.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	Septisel 10% Solution.
	Composition	Each litre contains: Di-decyl-di-methyl-ammonium bromide….10%
	Diary No. Date of R& I & fee	Rs.30,000/- (21004/26.07.2022)
	Pharmacological Group	External Liquid Preparation (disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	1 litre, 2.5 litre, 5 litre / Decontrolled
	Me-too status	BROMO-SEPT Solution. Registration No: 017054, by M/s SELMORE AGENCIES, Lahore.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Generic is not same as applied
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1021.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	SEPTISEL 50% SOLUTION. (Innovator's Specs)
	Composition	Each litre contains: Di-decyl-di-methyl-ammonium bromide….500gm
	Diary No. Date of R& I & fee	Rs.30,000/- (21010/26.07.2022)
	Pharmacological Group	External Liquid Preparation (disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	1 litre, 2.5 litre, 5 litre / Decontrolled
	Me-too status	BROMO-SEPT 50% Solution Registration No: 018818. by M/s SELMORE AGENCIES, Lahore.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
External Powder Preparation 5 Products / 5 Molecules		

1022.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	DELTA 5% POWDER.
	Composition	Each 100gm contain: Deltamethrin……..5gm
	Diary No. Date of R& I & fee	Rs.30,000/- (21005/23.07.2022)
	Pharmacological Group	External Powder Preparation.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	100gm , 500gm , 1Kg , 2.5kg / Decontrolled
	Me-too status	DELTAMETHRIN WP 5% (Wettable Powder) Registration No: 019561. By M/s EDGRO, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Generic not confirmed
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Decision: Approved.**	
1023.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	SCABICID POWDER.
	Composition	Each gm contains: Gamma Benzene Hexachloride……190mg Talcum……..810mg
	Diary No. Date of R& I & fee	Rs.30,000/- (21006/26.07.2022)
	Pharmacological Group	External Powder Preparation (Insecticide)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	250g, 500g, 1kg, 5kg / Decontrolled
	Me-too status	STARTOX POWDER Registration No: 026542 by M/s STAR LABORATORIES, Lahore.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1024.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	FENTEX POWDER. (Innovator's Specs)
	Composition	Each kg contains: Fenthion……..20g
	Diary No. Date of R& I & fee	Rs.30,000/- (21007/26.07.2022)
	Pharmacological Group	External Powder Preparation (Insecticide)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, 1 kg / Decontrolled
	Me-too status	FENTHION GR 2% Registration No: 021088 by M/s EDGRO, Karachi .
	GMP status	New Section Approval granted on 04-07-2022

	Remarks of the Evaluator.	Submitted generic of human product
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Decision: Approved.	
1025.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	MALAPHOS POWDER
	Composition	Each kg contains: Malathion ……..500g
	Diary No. Date of R& I & fee	Rs.30,000/- (21008/26.07.2022)
	Pharmacological Group	External Powder Preparation (Insecticide)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	250gm , 500gm , 1Kg , 5Kg , 10 Kg / Decontrolled
	Me-too status	MALATHION 50% Registration No: 023184 by M/s DADA JEE CORPORATION, Lahore
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Submitted generic of human product
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Decision: Approved.	
1026.	Name and address of manufacturer / Applicant	**"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."**
	Brand Name +Dosage Form + Strength	PROKILL Powder
	Composition	Alkyl (60% C_{14}, 30% C_{16}, 5%C_{12}, 5%C_{18}) dimethyl benzyl ammonium chloride… 40%. Inert Ingredient: urea….60%
	Diary No. Date of R& I & fee	Rs.30,000/- (21009/26.07.2022)
	Pharmacological Group	External Powder Preparation (Disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	250g , 500g , 1Kg , 5Kg / Decontrolled
	Me-too status	TIMSEN Powder Registration No: 043101 by M/s GHAZI BROTHERS, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Me-too not same as applied product
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

Central Licensing Board in its 286th meeting dated 11th May, 2022 approved following two sections of M/s D. Haans Pharma (Pvt.) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK:

i. Oral Powder Section (Penicillin)-Veterinary
ii. Liquid Injection (Veterinary)

	Liquid Injection (Veterinary) 41 Products / 10 Molecules	
1027	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Xenox Injection (50ml)**
	Composition	Each ml contains:- Oxytetracycline as HCl …… 300mg Flunixin Meglumin…….. 20mg
	Diary No. Date of R& I & fee	Dy No.21800: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic, Anti-emetic

	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Oxy Forte LA Injection (Attabak Pharma) Reg # 062185
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1028	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Xenox Injection (100ml)**
	Composition	Each ml contains:- Oxytetracycline as HCl …… 300mg Flunixin Meglumin …….. 20mg
	Diary No. Date of R& I & fee	Dy No.21801: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic, Anti-emetic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Oxy Forte LA Injection (Attabak Pharma) Reg # 062185
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1029	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Minarine Injection (10ml)**
	Composition	Each ml contains:- Diminazine Aceturate …… 105mg Antipyrine …….. 131mg
	Diary No. Date of R& I & fee	Dy No.21805: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Dianox Injection (Nawan Laboratories) Reg # 072674
	Remarks of the Evaluator	Formulation under discussion
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
1030	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Minarine Injection (50ml)**
	Composition	Each ml contains:- Diminazine Aceturate …… 105mg Antipyrine …….. 131mg
	Diary No. Date of R& I & fee	Dy No.21806: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications

	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Dianox Injection (Nawan Laboratories) Reg # 072674
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
1031	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Minarine Injection (100ml)**
	Composition	Each ml contains:- Diminazine Aceturate …… 105mg Antipyrine …….. 131mg
	Diary No. Date of R& I & fee	Dy No.21807: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Dianox Injection (Nawan Laboratories) Reg # 072674
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
1032	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 1% Injection (10ml)**
	Composition	Each 100ml contains:- Ivermectin …… 1g
	Diary No. Date of R& I & fee	Dy No.21835: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (Selmore Pharma) Reg # 034595
	Remarks of the Evaluator	
	Decision: Approved	
1033	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 1% Injection (50ml)**
	Composition	Each 100ml contains:- Ivermectin …… 1g
	Diary No. Date of R& I & fee	Dy No.21836: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (Selmore Pharma) Reg # 034595
	Remarks of the Evaluator	
	Decision: Approved	
1034	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber

	Brand Name +Dosage Form + Strength	**Iver Hans 1% Injection (100ml)**
	Composition	Each 100ml contains:- Ivermectin …… 1g
	Diary No. Date of R& I & fee	Dy No.21837: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (Selmore Pharma) Reg # 034595
	Remarks of the Evaluator	
	Decision: Approved	
1035	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 1% Injection (500ml)**
	Composition	Each 100ml contains:- Ivermectin …… 1g
	Diary No. Date of R& I & fee	Dy No. 21838: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	500ml/Decontrolled
	Me-too status (with strength and dosage form)	Primec-10 Injection (Prix Pharma) Reg # 072696
	Remarks of the Evaluator	
	Decision: Approved	
1036	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 2% Injection (10ml)**
	Composition	Each ml contains:- Ivermectin …… 20mg
	Diary No. Date of R& I & fee	Dy No.21832: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Selmec Injection (Selmore Pharma) Reg # 071087
	Remarks of the Evaluator	
	Decision: Approved	
1037	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 2% Injection (50ml)**
	Composition	Each ml contains:- Ivermectin …… 20mg
	Diary No. Date of R& I & fee	Dy No.21833: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	50ml/Decontrolled

	Me-too status (with strength and dosage form)	Selmec Injection (Selmore Pharma) Reg # 071087
	Remarks of the Evaluator	
	Decision: Approved	
1038	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 2% Injection (100ml)**
	Composition	Each ml contains:- Ivermectin …… 20mg
	Diary No. Date of R& I & fee	Dy No.21834: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Selmec Injection (Selmore Pharma) Reg # 071087
	Remarks of the Evaluator	
	Decision: Approved	
1039	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 3.15% Injection (10ml)**
	Composition	Each 100ml contains:- Ivermectin …… 3.15%
	Diary No. Date of R& I & fee	Dy No. : 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Elvomec Star Injection (Elko Organization) Reg # 063728
	Remarks of the Evaluator	
	Decision: Approved	
1040	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 3.15% Injection (50ml)**
	Composition	Each 100ml contains:- Ivermectin …… 3.15%
	Diary No. Date of R& I & fee	Dy No.21830: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Elvomec Star Injection (Elko Organization) Reg # 063728
	Remarks of the Evaluator	
	Decision: Approved	
1041	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Iver Hans 3.15% Injection (100ml)**

	Composition	Each 100ml contains:- Ivermectin …… 3.15%
	Diary No. Date of R& I & fee	Dy No. 21831 : 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Elvomec Star Injection (Elko Organization) Reg # 063728
	Remarks of the Evaluator	
	Decision: Approved	
1042	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Roci Hans 10% Injection (50ml)**
	Composition	Each 100ml contains:- Enrofloxacin …… 10g
	Diary No. Date of R& I & fee	Dy No. 21798 : 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Eflocin 10% Injection (Eros Pharma) Reg # 071026
	Remarks of the Evaluator	
	Decision: Approved	
1043	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Roci Hans 10% Injection (100ml)**
	Composition	Each 100ml contains:- Enrofloxacin …… 10g
	Diary No. Date of R& I & fee	Dy No. 21799: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Eflocin 10% Injection (Eros Pharma) Reg # 071026
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1044	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Roci Hans 20% Injection (10ml)**
	Composition	Each 100ml contains:- Enrofloxacin …… 20g
	Diary No. Date of R& I & fee	Dy No. 21820: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled

	Me-too status (with strength and dosage form)	Eflocin 20% Injection (Eros Pharma) Reg # 063766
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1045.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Roci Hans 20% Injection (50ml)**
	Composition	Each 100ml contains:- Enrofloxacin …… 20g
	Diary No. Date of R& I & fee	Dy No. 21821 : 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Eflocin 20% Injection (Eros Pharma) Reg # 063766
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1046.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Roci Hans 20% Injection (100ml)**
	Composition	Each 100ml contains:- Enrofloxacin …… 20g
	Diary No. Date of R& I & fee	Dy No.21822: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Eflocin 20% Injection (Eros Pharma) Reg # 063766
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1047.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Bupra Hans Injection (10ml)**
	Composition	Each ml contains:- Buparvaquone …… 50mg
	Diary No. Date of R& I & fee	Dy No. 21817: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic, hydroxynaphthoquinones
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Zubalex Injection (Zakfas Pharma) Reg # 063594
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1048	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Bupra Hans Injection (50ml)**
	Composition	Each ml contains:- Buparvaquone …… 50mg
	Diary No. Date of R& I & fee	Dy No. 21818: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic, hydroxynaphthoquinones
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Zubalex Injection (Zakfas Pharma) Reg # 063594
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1049	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Bupra Hans Injection (100ml)**
	Composition	Each ml contains:- Buparvaquone …… 50mg
	Diary No. Date of R& I & fee	Dy No.21819: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic, hydroxynaphthoquinones
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Zubalex Injection (Zakfas Pharma) Reg # 063594
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1050	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Vit ADE Hans Injection (10ml)**
	Composition	Each ml contains:- Vitamin A …… 80,000IU Vitamin D3 ……. 40,000IU Vitamin E …… 20mg
	Diary No. Date of R& I & fee	Dy No.21802: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	3 Vitz Injection (Epoch Pharma) Reg # 069614
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1051	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Vit ADE Hans Injection (50ml)**
	Composition	Each ml contains:- Vitamin A …… 80,000IU Vitamin D3 …….. 40,000IU Vitamin E …… 20mg
	Diary No. Date of R& I & fee	Dy No. 21803: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	3 Vitz Injection (Epoch Pharma) Reg # 069614
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1052	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Vit ADE Hans Injection (100ml)**
	Composition	Each ml contains:- Vitamin A …… 80,000IU Vitamin D3 …….. 40,000IU Vitamin E …… 20mg
	Diary No. Date of R& I & fee	Dy No.21804: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	3 Vitz Injection (Epoch Pharma) Reg # 069614
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1053	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Amino Hans Injection (100ml)**
	Composition	Each 100ml contains:- L-Carnitine ……..……. 500mg Thiotic acid ……..……..… 20mg Pyridoxine HCl ……. 15mg DL-Acetylmethionine …… 2000mg L-Arginine ……. 240mg L-Ornithine …… 120mg L-Citruline …… 120mg L-Lysine …… 50mg Glycine ……. 150mg Taurine ……. 150mg Aspartic acid …….. 150mg

		Glutamic acid ……. 150mg Fructose ……. 5000mg Sorbitol ……. 8000mg
	Diary No. Date of R& I & fee	Dy No. 21816: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Multimino-V Injection (Selmore Pharma) Reg # 058712
	Remarks of the Evaluator	
	Decision: Deferred for evidence of availability of testing facility required for the analysis of amino acid ingredients of the applied formulation.	
1054	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Amino Hans Injection (250ml)**
	Composition	Each 100ml contains:- L-Carnitine ……..……. 500mg Thiotic acid ……..……..… 20mg Pyridoxine HCl ……. 15mg DL-Acetylmethionine …… 2000mg L-Arginine ……. 240mg L-Ornithine …… 120mg L-Citruline …… 120mg L-Lysine …… 50mg Glycine ……. 150mg Taurine ……. 150mg Aspartic acid …….. 150mg Glutamic acid ……. 150mg Fructose ……. 5000mg Sorbitol ……. 8000mg
	Diary No. Date of R& I & fee	Dy No.21815: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	250ml/Decontrolled
	Me-too status (with strength and dosage form)	Multimino-V Injection (Selmore Pharma) Reg # 058712
	Remarks of the Evaluator	
	Decision: Deferred for evidence of availability of testing facility required for the analysis of amino acid ingredients of the applied formulation.	
1055	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Amino Hans Injection (500ml)**
	Composition	Each 100ml contains:- L-Carnitine ……..……. 500mg Thiotic acid ……..……..… 20mg Pyridoxine HCl ……. 15mg DL-Acetylmethionine …… 2000mg L-Arginine ……. 240mg L-Ornithine …… 120mg L-Citruline …… 120mg L-Lysine …… 50mg Glycine ……. 150mg Taurine ……. 150mg

		Aspartic acid …….. 150mg Glutamic acid ……. 150mg Fructose ……. 5000mg Sorbitol ……. 8000mg
	Diary No. Date of R& I & fee	Dy No. 21814: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	500ml/Decontrolled
	Me-too status (with strength and dosage form)	Multimino-V Injection (Selmore Pharma) Reg # 058712
	Remarks of the Evaluator	
	Decision: Deferred for evidence of availability of testing facility required for the analysis of amino acid ingredients of the applied formulation.	
1056	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Flunix Hans Injection (10ml)**
	Composition	Each ml contains:- Flunixin Meglumin ……. 50mg
	Diary No. Date of R& I & fee	Dy No. 21823: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Analgesic, Anti-Inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxicon Injection (Vetcon Pharma) Reg # 058704
	Remarks of the Evaluator	
	Decision:Approved	
1057	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Flunix Hans Injection (50ml)**
	Composition	Each ml contains:- Flunixin Meglumin ……. 50mg
	Diary No. Date of R& I & fee	Dy No. 21824: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Analgesic, Anti-Inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxicon Injection (Vetcon Pharma) Reg # 058704
	Remarks of the Evaluator	
	Decision: Approved	
1058	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Flunix Hans Injection (100ml)**
	Composition	Each ml contains:- Flunixin Meglumin ……. 50mg
	Diary No. Date of R& I & fee	Dy No. 21825: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Analgesic, Anti-Inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP

	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxicon Injection (Vetcon Pharma) Reg # 058704
	Remarks of the Evaluator	
	Decision: Approved	
1059	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Flunix Hans 8.3 Injection (10ml)**
	Composition	Each ml contains:- Flunixin Meglumin ……. 83mg
	Diary No. Date of R& I & fee	Dy No. 21826: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Analgesic, Anti-Inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Nixsym Injection (Symans Pharma) Reg # 063852
	Remarks of the Evaluator	
	Decision: Approved	
1060	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Flunix Hans 8.3 Injection (50ml)**
	Composition	Each ml contains:- Flunixin Meglumin …… 83mg
	Diary No. Date of R& I & fee	Dy No. 21823: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Analgesic, Anti-Inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Nixsym Injection (Symans Pharma) Reg # 063852
	Remarks of the Evaluator	
	Decision: Approved	
1061	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Flunix Hans 8.3 Injection (100ml)**
	Composition	Each ml contains:- Flunixin Meglumin …… 83mg
	Diary No. Date of R& I & fee	Dy No. 21828: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Analgesic, Anti-Inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Nixsym Injection (Symans Pharma) Reg # 063852
	Remarks of the Evaluator	
	Decision: Approved	
1062	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Hansi Pro 10% Injection (10ml)**
	Composition	Each ml contains:-

		Ketoprofen ……. 100mg
	Diary No. Date of R& I & fee	Dy No. 21808: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP Vet Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Fentac Injection (A & K Pharma) Reg # 075796
	Remarks of the Evaluator	
	Decision: Approved	
1063	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Hansi Pro 10% Injection (50ml)**
	Composition	Each ml contains:- Ketoprofen ……. 100mg
	Diary No. Date of R& I & fee	Dy No. 21809: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP Vet Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Fentac Injection (A & K Pharma) Reg # 075796
	Remarks of the Evaluator	
	Decision: Approved	
1064	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Hansi Pro 10% Injection (100ml)**
	Composition	Each ml contains:- Ketoprofen ……. 100mg
	Diary No. Date of R& I & fee	Dy No.21810: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP Vet Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Fentac Injection (A & K Pharma) Reg # 075796
	Remarks of the Evaluator	
	Decision: Approved	
1065	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Mido Hans Injection (10ml)**
	Composition	Each ml contains:- Imidocarb Dipropionate ……. 120mg
	Diary No. Date of R& I & fee	Dy No. 21811: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Durazol Injection (My Lab Pharma) Reg # 078204
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1066	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Mido Hans Injection (50ml)**
	Composition	Each ml contains:- Imidocarb Dipropionate ….. 120mg
	Diary No. Date of R& I & fee	Dy No.21812: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Durazol Injection (My Lab Pharma) Reg # 078204
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
1067	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	**Mido Hans Injection (100ml)**
	Composition	Each ml contains:- Imidocarb Dipropionate ……. 120mg
	Diary No. Date of R& I & fee	Dy No. 21813: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Durazol Injection (My Lab Pharma) Reg # 078204
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
Central Licensing Board in its 286th meeting dated 11th May, 2022 approved following two sections of M/s D. Haans Pharma (Pvt.) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK:		
Oral Powder Section (Penicillin)-Veterinary 23 Products / 10 Molecules		
1068	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amoxy Hans 50% Oral W/S Powder
	Composition	Each 100g contains:- Amoxicillin as trihydrate …… 50g
	Diary No. Date of R& I & fee	Dy No.21789: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP Vet Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Rymox-50 Powder (Zumras Pharma) Reg # 069665
	Remarks of the Evaluator	
	Decision: Approved	

1069	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amoxy Hans 60% Oral W/S Powder
	Composition	Each g contains:- Amoxicillin as trihydrate …… 600mg
	Diary No. Date of R& I & fee	Dy No. 21790: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP Vet Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Triger Powder (Selmore Pharma) Reg # 080958
	Remarks of the Evaluator	
	Decision: Approved	
1070	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amoxy Hans 70% Oral W/S Powder
	Composition	Each 100g contains:- Amoxicillin trihydrate BP ….. 80g eq to 70g Amoxicillin
	Diary No. Date of R& I & fee	Dy No. 21791: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP Vet Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Primox 70% Powder (Prix Pharma) Reg # 074032
	Remarks of the Evaluator	
	Decision: Approved	
1071	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Himox-C Hans 15% W/S Powder
	Composition	Each 100g contains:- Amoxicillin trihydrate BP …….. 15g Colistin sulphate BP …….. 5MIU
	Diary No. Date of R& I & fee	Dy No.21793: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Coli-Amox w/s Powder (Farm Aid Group) Reg # 029638
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference Composition in covering letter and form-5 is not same.
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1072	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Himox-C Hans 15/550 W/S Powder
	Composition	Each 1000g contains:- Amoxicillin trihydrate BP …….. 15%

		Colistin sulphate BP …….. 550MIU
	Diary No. Date of R& I & fee	Dy No. 21792: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Amcol w/s Powder (Inshal Pharma) Reg # 073944
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference Composition in covering letter and form-5 is not same.
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1073.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Himox-C Hans 20% W/S Powder
	Composition	Each 1000g contains:- Amoxicillin trihydrate BP …….. 20% Colistin sulphate BP …….. 500MIU
	Diary No. Date of R& I & fee	Dy No.21794: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Amoxyprep w/s Powder (Inshal Pharma) Reg # 073945
	Remarks of the Evaluator	Amoxicillin trihydrate salt for is not as per reference Composition in covering letter and form-5 is not same.
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1074.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Himox-C Hans 23% W/S Powder
	Composition	Each 100g contains:- Amoxicillin trihydrate BP …….. 23g Colistin sulphate BP …….. 100MIU
	Diary No. Date of R& I & fee	Dy No.21795/ 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Penta Mox w/s Powder (Biogen Pharma) Reg # 071018
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference Composition in covering letter and form-5 is not same
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1075.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Himox-C Hans 50% W/S Powder

	Composition	Each 100g contains:- Amoxicillin as trihydrate BP …….. 50g Colistin sulphate BP …….. 50MIU
	Diary No. Date of R& I & fee	Dy No.21796: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Amox-C Maarson w/s Powder (Attabak Pharma) Reg # 071054
	Remarks of the Evaluator	Composition in covering letter and form-5 is not same.
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1076	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Himox-C Hans 80% W/S Powder
	Composition	Each 100g contains:- Amoxicillin as trihydrate BP …….. 20g Colistin sulphate BP …….. 80MIU
	Diary No. Date of R& I & fee	Dy No.21798: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Amoxitin w/s Powder (Attabak Pharma) Reg # 071062
	Remarks of the Evaluator	Composition in covering letter and form-5 is not same.
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1077	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amotin-D 15% W/S Powder
	Composition	Each Kg contains:- Amoxicillin trihydrate ……..…….. 150g Colistin sulphate …….. 500MIU Dextrose Anhydrous qs …….. 1000g
	Diary No. Date of R& I & fee	Dy No.21785 : 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Potencil w/s Powder (Decent Pharma) Reg # 079843
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference Composition in covering letter and form-5 is not same.
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1078	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber

	Brand Name +Dosage Form + Strength	Amotin-D 20% W/S Powder
	Composition	Each 1000g contains:- Amoxicillin trihydrate ……..…….. 200g Colistin sulphate …….. 800MIU Dextrose Anhydrous qs …….. 1000g
	Diary No. Date of R& I & fee	Dy No. : 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Ascot w/s Powder (Decent Pharma) Reg # 079841
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference Composition in covering letter and form-5 is not same.
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1079	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amotin-D 23% W/S Powder
	Composition	Each 1000g contains:- Amoxicillin as trihydrate ……..…….. 230g Colistin sulphate …….. 1000MIU Dextrose Anhydrous qs …….. 1000g
	Diary No. Date of R& I & fee	Dy No.21787: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Senacilin w/s Powder (Decent Pharma) Reg # 079845
	Remarks of the Evaluator	Composition in covering letter and form-5 is not same.
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1080	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amotin-D 50% W/S Powder
	Composition	Each 100g contains:- Amoxicillin trihydrate ……..…….. 50g Colistin sulphate …….. 50MIU Dextrose Anhydrous qs …….. 100g
	Diary No. Date of R& I & fee	Dy No. 21787: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Euromox-50 w/s Powder (Decent Pharma) Reg # 080156
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference Composition in covering letter and form-5 is not same.

	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1081	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Timox-L 10 W/S Powder
	Composition	Each 1000g contains:- Lincomycin HCl BP …….. 8.8g Spectinomycin 2HCl BP …….. 8.8g Amoxicillin trihydrate BP ……..…….. 20g
	Diary No. Date of R& I & fee	Dy No. 21783: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Lincosac-200 w/s Powder (Sanna Labortories) Reg # 081696
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1082	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Timox-L 20 W/S Powder
	Composition	Each 100g contains:- Lincomycin HCl BP …….. 8.8g Spectinomycin 2HCl BP …….. 8.8g Amoxicillin trihydrate BP ……..…….. 20g
	Diary No. Date of R& I & fee	Dy No.21784: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	T-Moxin w/s Powder (Farm Aid Group) Reg # 087198
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1083	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Timox-L W/S Powder
	Composition	Each 100g contains:- Lincomycin HCl BP …….. 5g Spectinomycin HCl BP …….. 5g Amoxicillin trihydrate BP ……..…….. 10g
	Diary No. Date of R& I & fee	Dy No. 21782: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled

	Me-too status (with strength and dosage form)	Limox-P w/s Powder (Bio-Labs) Reg # 043174
	Remarks of the Evaluator	Amoxicillin trihydrate salt form is not as per reference
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1084	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	E Hans-2000 Powder
	Composition	Each g contains:- Amoxicillin trihydrate eq to base BP ……..... 200mg Lincomycin HCl eq to base BP ……..... 88mg Spectinomycin Sulphate eq to base BP …….. 88mg Vitamin E Acetate BP …… 30mg
	Diary No. Date of R& I & fee	Dy No.21775: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics, Vitamin
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Lincomoxel plus w/s Powder (Selmore Pharma) Reg # 080960
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1085	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	ANC-Hans W/S Powder
	Composition	Each Kg contains:- Amoxicillin as trihydrate BP ……..…….. 100g Colistin sulphate BP ……..…….. 50g Neomycin sulphate BP …….. 200g
	Diary No. Date of R& I & fee	Dy No. 21776: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Neo AC w/s Powder (Decent Pharma) Reg # 079844
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1086	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Procol Mix Powder
	Composition	Each Kg contains:- Procaine Penicillin BP ……..…….. 12g Streptomycin sulphate BP ……..….. 36g Zinc Bacitracin BP ……..…….. 52g
	Diary No. Date of R& I & fee	Dy No. 21777: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics

	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	SPZ 100 w/s Powder (Symans Pharma) Reg # 072671
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1087	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Zincol Mix-1000 Powder
	Composition	Each Kg contains:- Procaine Penicillin BP ……..…….. 12g Streptomycin sulphate BP ……..….. 36g Colistin sulphate BP …… 60MIU Zinc Bacitracin BP ……..…….. 52g
	Diary No. Date of R& I & fee	Dy No. 21780: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	500g, Kg, 2.5Kg, 5Kg, 25Kg/Decontrolled
	Me-too status (with strength and dosage form)	Zeptocol w/s Powder (Selmore Pharma) Reg # 080962
	Remarks of the Evaluator	Composition in covering letter and form-5 is not same.
	Decision: Referred to EWG on veterinary drugs.	
1088	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Zincol Mix-2000 Powder
	Composition	Each Kg contains:- Procaine Penicillin BP ……..…….. 16g Streptomycin sulphate BP ……..….. 40g Colistin sulphate BP …… 80MIU Zinc Bacitracin 10% BP …….. 100g
	Diary No. Date of R& I & fee	Dy No. 21781: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	500g, Kg, 2.5Kg, 5Kg, 25Kg/Decontrolled
	Me-too status (with strength and dosage form)	Colibac-SP 160 w/s Powder (Nawan Laboratories) Reg # 082488
	Remarks of the Evaluator	Composition in covering letter and form-5 is not same.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
1089	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Neo Cane-Z Powder
	Composition	Each Kg contains:- Procaine Penicillin BP ……..…….. 12g Streptomycin sulphate BP ……..….. 36g Neomycin sulphate BP …… 10g Zinc Bacitracin BP ……..…….. 52g
	Diary No. Date of R& I & fee	Dy No. 21778: 02.08.2022

		PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	500g, Kg, 2.5Kg, 5Kg, 25Kg/Decontrolled
	Me-too status (with strength and dosage form)	Biocillin-SN w/s Powder (Bio-Labs Pharma) Reg # 097941
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
1090	**Name and address of manufacturer / Applicant**	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Pheno Hans W/S Powder
	Composition	Each g contains:- Phenoxymethylpenicillin ……. 293mg/g eq. to Potassium phenoxymethylpenicillin ……..…….. 325mg/g
	Diary No. Date of R& I & fee	Dy No. 21779: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	100g, 250g, 500g, Kg/Decontrolled
	Me-too status (with strength and dosage form)	Phenoxypen w/s Powder (Tec-man international) Reg # 081303 Fenapen w/s Powder (My-Lab Pharma) Reg # 106727
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

Agenda of Evaluator PEC-XVIII

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27479 dated 05.10.2021
	Details of fee submitted	PKR 30000/- dated 28.07.2021 (Slip No. 12707594008)
	The proposed proprietary name / brand name	Brainzon 10mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate…… 10mg
	Pharmaceutical form of applied drug	White Color Round Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blockers
	Reference to Finished product specifications	In-House
	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablet 10mg of Takeda Pharmaceuticals Ltd (PMDA Approved)
	For generic drugs (me-too status)	Vocinti Tablet 10mg f The Searle Company Karachi.
	GMP status of the Finished product manufacturer	GMP certificate was issued to the firm by DRAP Peshawar dated .03.06.2019
	Name and address of API manufacturer.	M/s Ami Lifesciences Private Limited Block No. 82/B ECP road and Kharakhadi 391450 Taluka: Padra district Vadodara Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure (including dissolution testing) and batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product Vocinti 20mg Tablets of M/s Takeda CDP has been performed against the aforesaid brand in three media. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted.
STABILITY STUDY DATA		

Manufacturer of API	M/s Ami Lifesciences Private Limited Address: Block No.82/B, ECP Road Taluka Padra District, Vadodara Gujarat, INDIA		
API Lot No.	VPF/30051020		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	T-06	T-07	T-08
Batch Size	1200 tab	1200 tab	1200 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	22-06-2020	22-06-2020	22-06-2020
No. of Batches	03		

Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any evidence/ document.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License to manufacture drugs issued by Food and Drug Control Administration Gujarat State India.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided the copy of Airway Bill along with shipment details. However, at the time of inspection panel shall confirm the evidence of import API specifically DRAP attested invoice for the import of Vonoprazan Fumarate having Batch No. VPF/300512020 Mfg. Date 08.20220, Expiry/ Retest date 08.2023 Further the panel shall also confirm the import of reference standard as COA of the same is not submitted.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided
Remarks of Evaluator:		
2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27480 dated 05.10.2021
	Details of fee submitted	PKR 30000/- dated 28.07.2021 (Slip No. 48056752)
	The proposed proprietary name / brand name	Brainzon 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate…… 20mg
	Pharmaceutical form of applied drug	White Color Round Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blockers
	Reference to Finished product specifications	In-House
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablet 20mg of Takeda Pharmaceuticals Ltd (PMDA Approved)
	For generic drugs (me-too status)	Vocinti Tablet 20mg f The Searle Company Karachi.
	GMP status of the Finished product manufacturer	GMP certificate was issued to the firm by DRAP Peshawar dated .03.06.2019
	Name and address of API manufacturer.	M/s Ami Lifesciences Private Limited Block No. 82/B ECP road and Kharakhadi 391450 Taluka: Padra district Vadodara Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure (including dissolution testing)and batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product Vocinti 20mg Tablets CDP has been performed against the aforesaid brand in three media. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Ami Lifesciences Private Limited Address: Block No.82/B, ECP Road Taluka Padra District, Vadodara Gujarat, INDIA		
API Lot No.	VPF/30051020		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	T-06	T-07	T-08
Batch Size	1200 tab	1200 tab	1200 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	22-06-2020	22-06-2020	22-06-2020
No. of Batches	03		

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any evidence/ document.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License to manufacture drugs issued by Food and Drug Control Administration Gujarat State India.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided the copy of Airway Bill along with shipment details. However, at the time of inspection panel shall confirm the evidence of import API specifically DRAP attested invoice for the import of Vonoprazan Fumarate having Batch No. VPF/300512020 Mfg. Date 08.20220, Expiry/ Retest date 08.2023 Further the panel shall also confirm the import of reference standard as COA of the same is not submitted.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided

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

Remarks of Evaluator:

INSPECTION FOR VERIFICATION OF DATA

Q.No.1	Do you have documents confirming the import of Vonoprazan as fumarate API?	The firm provided following documents to confirm the import of Vonoprazan as fumarate API i.e., 1. GD dated 23/08/2020, IGM/EGM No ipaf-1705-2020. 2. Copy of import invoice No. EXP/I/20-21/0107 dated 05.08.2020, Vonoprazan Fumarate IH, B. No. VPF/30051020 Mfg. date 08/2020, Retest date 08/2023. 3. COA. DRAP attested invoice is not provided by the firm. **(Annexure 01)**
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	The firm informed that selection of API manufacturer was based upon its GMP Certification and availability of DMF (open part). The firm agreed to provide adequate sample for initial testing for prequalification. The API manufacturer qualified their vendor qualification SOP.
Q.No.3	Do you have documents confirming the import of Vonoprazan as fumarate reference standard and impurity standards?	The firm has provided copy of COA of reference/working standard, Batch No VPF/30901118, Mfg. Date: March-2020, provided by API manufacturer, copy attached **(Annexure 02).** However, API manufacturer did not provide impurities standard.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Yes, certificate of Analysis of the API and working standards (Vonoprazan as fumarate) are provided. However, the API manufacturer did not provide impurities standard.
Q.No.5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, approval of API or GMP certificate of API manufacture AMI LIFE -SCIENCES No G/25/1704 valid till 14-06-2025 is available. **(Annexure 03)**
Q.No.6	Do you use API manufacturer method of testing?	Yes, the firm use API manufacturer method of testing, also verification of API performed by the firm as per API manufacturer method.
Q.No.7	Do you have stability studies reports on API?	Yes, stability studies report on API (Vonoprazan) are provided by the API manufacturer in DMF.
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	No, the stability testing has not been performed as per SIM method and degradation product, however firm conduct stability study as per ICH guidelines.
Q.No.9	Do you have method for quantifying the impurities in the API?	Yes, the firm have API manufacturer method of testing impurities.
Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Working standard approx. 500mg available at time of inspection.
Q.No.11	Have you used pharmaceutical grade excipients?	Yes, the firm uses imported pharmaceutical grade excipient, which are procured from local suppliers. Vender qualification SOP is followed.
Q.No.12	Do you have documents confirming the import of the used excipients?	The firm purchased excipients locally (imported excipients), COA and Evidence attached **(Annexure 04).**

Q.No.13	Do you have test reports and other records on the excipients used?	Yes, test reports and other records of the excipients used and copy available with the firm is attached. **(Annexure 05).**
Q.No.14	Do you have written and authorized protocols for the development of Vonoprazan as fumarate tablets?	The firm provided written and authorized protocols for the development of Vonoprazan tablet.
Q.No.15	Have you performed Drug-excipient compatibility studies?	Drug-excipient compatibility studies not performed by the firm, however Firm used brand leader formulation already studied by them copy attached **(Annexure 06).**
Q.No.16	Have you performed comparative dissolution studies?	Yes, the firm performed comparative dissolution studies in three media details attached **(Annexure 07).**
Q.No.17	Do you have product development (R&D) section	No separate dedicated product development (R&D) section is established by the firm. The firm was advised to establish R&D section with required staff on urgent basis.
Q.No.18	Do you have necessary Equipments available in product development section for development of Vonoprazan as fumarate tablets?	Manual/ production facilities are being utilized by the firm for said purpose. The firm is committed to establish R&D section as discussed above.
Q.No.19	Are the Equipments in product development section qualified?	As above.
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	As above.
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	As above.
Q.No.22	Have you manufactured three stability batches for the stability studies of Vonoprazan as fumarate tablets as required?	Yes, the firm has manufactured three stability batches for the stability studies of Vonoprazan tablets as required Brainzon 10mg B.NO: T-03, T-04, T-05 Mfg. date:09-2020 Exp date:09-2022, B. Size:1200 Tablet each. Brainzon 20mg B.NO: T-06, T-07, T-08 Mfg. date:09-2020 Exp date:09-2022 B. Size:1200 Tablet each. Printed packs were also checked which were placed in stability chambers.
Q.No.23	What was the criteria for fixing the batch size of stability batches?	The firm said that the criteria for fixing the batch size of stability batches is the number of tablets per testing frequency and number of testing frequencies while keeping in view the decision of Registration Board (RB) in its 249th Meeting.
Q.No.24	Do you have complete record of production of stability batches?	Yes, batch manufacturing record available

Q.No.25	Do you have protocols for stability testing of stability batches?	Yes, firm have protocols for stability testing of stability batches as per ICH guidelines.
Q.No.26	Do you have developed and validated the method for testing of stability batches?	Yes, the firm has developed and validated the method for testing of stability batches summary report attached **(Annexure 08).**
Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	NA
Q.No.28	Do you have documents confirming the qualification of Equipments / instruments being used in the test and analysis of Vonoprazan as fumarate API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug. The panel checked the same and found satisfactory.
Q.No.29	Do your method of analysis stability indicate?	Degradation study not performed by firm.
Q.No.30	Do your HPLC software is 21CFR compliant?	Water 600 pump 486 Detector Empower 2 software 21 CFR Complies
Q.No.31	Can you show Audit Trail reports on Vonoprazan as fumarate testing?	Audit trail on the testing reports is found available.
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	Only Stability batches available with the firm.
Q.No.33	Do you have commitment batches kept on stability testing?	Yes
Q.No.34	Do you have valid calibration status for the Equipments used in Vonoprazan as fumarate tablets production in analysis?	The firm has valid calibration status for the equipment used in production and analysis of Vonoprazan **(Annexure 09)**
Q.No.35	Do proper and continuous monitoring and control are available for stability chamber?	The firm has two stability chamber local made, manual logbooks maintained with electricity backup.
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are in compliance.
Q.No.36	Power supply Backup	Separate generator available for both QC and Production. Start within minute after light breakage 100KW for Production 25KW for QC Department
With reference to queries, reply is placed at S. No. 1&3. Based on physical inspection and data reviewed, panel has verified the stability data provided by the firm.		
Decision: Registration Board approved Brainzon 10& 20mg Tablet (Vonoprazan as Fumarate) with following conditions: **i. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**		

	ii. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.	
3.	**Name, address of Applicant / Importer**	**M/s Graton Pharma, Office No. 501 & 502, 5th Floor Plot No. 42-C/2 Lane-8 Bukhari Commercial phase -VI D.H.A Karachi**
	Details of Drug Sale License of importer	**License No:** DHSKDK (drug)/-2225 dated 24.10.2019 **Address:** Office No. 501 & 502, 5th Floor Plot No. 42-C/2 Lane-8 Bukhari Commercial phase -VI D.H.A Karachi **Address of Godown:** NA **Validity:** 22.10.2021 **Status:** Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Jodas Expoim Pvt Limited, Plot No. 55 Phase III Biotech Park Karkapatla(V) Markook(M) Siddipet (D) Telangana India.
	Name, address of manufacturer(s)	M/s Jodas Expoim Pvt Limited, Plot No. 55 Phase III Biotech Park Karkapatla(V) Markook(M) Siddipet (D) Telangana India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP L.Dis. No. 3349/E/2020 dated 29.10.2020 indicating that Geftinib Tables 250mg (Gefiressa) is licensed and on market in exporting country. **Validity:** 26.02.2023
	Details of letter of authorization / sole agency agreement	Firm has submitted original legalized Authority letter issued by Managing Director of Jodas Expoim Private Limited Telangana India in name of M/s Graton Pharma Karachi.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 28225 dated 13.10.2021
	Details of fee submitted	PKR /-: 50000/- dated 26.03.2021 and 25000/.- dated 13.09.2021 **75000/- dated 24.08.2022**
	The proposed proprietary name / brand name	Gefiton Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Gefitinib…..250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug, Protein Kinase Inhibitor
	Reference to Finished product specifications	In house

	Proposed Pack size	10's Blister Packing of PVC film & Alu Foil 30's HDPE Bottle
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Iressa Tablets of AstraZeneca USFDA Approved.
	For generic drugs (me-too status)	Gefitec Tablets 250mg of Revive Healthcare Lahore (Reg No: 087683)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Cydmax (formerly ACEBRIGHT India) (India) Pharma Pvt Limited No.77D & 116/117 KIADB Industrial Area Jigani Bangalore Karnataka India
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 60 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Irresa of astrazeneca
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 75% ± 5% for 24 months
Decision:	**Approved with Innovator Specifications as per Inspection Policy of manufacturers abroad for finished drugs.**	
4.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block C, Faisal Town Lahore.**

	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3302) issued on 28.07.2020 by Government of the People's Republic of Bangladesh, Ministry of Health & Family Welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3567 dated 01.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 14.12.2020
	The proposed proprietary name / brand name	Ponatinix 45 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ponatinib Hydrochloride equivalent to Ponatinib…...45mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack of 30's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Iclusig Tablets USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Lianyungang Jari Pharmaceutical Co., ltd No. 18 Zhenhua Road, Lianyungang China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months
Evaluation by PEC:		
The firm was asked to clarify that the comparative dissolution data submitted is conducted by Alpha Laboratories Mumbai India rather than manufacturer. The firm submitted that for more consistency and precision new did comparative dissolution profile report & F2 calculation from third party i.e. Alpha Laboratories India since in future we will conduct BE study by assistance of Alpha Laboratories India.		
Decision: Deferred for following points: **i. Justification for conducting Comparative Dissolution studies at "M/s Alpha laboratories India", instead of M/s Beacon Pharmaceuticals Bangladesh.** **ii. Regulatory status of Alpha Laboratories India, whether it is licensed entity or otherwise.**		
5.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block C, Faisal Town Lahore.**

	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3302) issued on 28.07.2020 by Government of the People's Republic of Bangladesh, Ministry of Health & Family Welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3567 dated 01.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 14.12.2020
	The proposed proprietary name / brand name	Ponatinix 45 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ponatinib Hydrochloride equivalent to Ponatinib…...45mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack of 30's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Iclusig Tablets USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Lianyungang Jari Pharmaceutical Co., ltd No. 18 Zhenhua Road, Lianyungang China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months
Evaluation by PEC:		
The firm was asked to clarify that the comparative dissolution data submitted is conducted by Alpha Laboratories Mumbai India rather than manufacturer. The firm submitted that for more consistency and precision new did comparative dissolution profile report & F2 calculation from third party i.e. Alpha Laboratories India since in future we will conduct BE study by assistance of Alpha Laboratories India.		
Decision: Deferred for following points: **i. Justification for conducting Comparative Dissolution studies at "M/s Alpha laboratories India", instead of M/s Beacon Pharmaceuticals Bangladesh.** **ii. Regulatory status of Alpha Laboratories India, whether it is licensed entity or otherwise.**		
6.	**Name, address of Applicant / Importer**	**M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan**

	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd floor plaza 60, commercial block K, phase 1 DHA, Distt. Lahore **Address of Godown:** NA **Validity:** 24-02-2023. **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	JARI Pharmaceutical Co., Ltd. 18 Zhenhua Road, Lianyungang City, People's Republic of China, 222006
	Name, address of manufacturer(s)	JARI Pharmaceutical Co., Ltd. 18 Zhenhua Road, Lianyungang City, People's Republic of China, 222006
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted legalized CoPP Certificate (No. JS20210116) dated 04.02.2021 issued by Jiangsu Drug Administration Nanjing Jiangsu China. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized copy of agreement between JARI Pharmaceutical Co., Ltd. China (manufacturer) & Liaoning Hongyuan Pharmaceutical Co., Ltd China (exporter) and AMB KH Enterprise Pvt Limited Lahore (importer).
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27483: 05-10-2021
	Details of fee submitted	PKR 150,030/-: 26-05-2021
	The proposed proprietary name / brand name	**GEMICA INJECTION 200mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Gemcitabine Hydrochloride eq. to Gemcitabine …….200mg
	Pharmaceutical form of applied drug	Lyophilized powder for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic
	Reference to Finished product specifications	Chinese Pharmacopeia
	Proposed Pack size	1's Vial
	Proposed unit price	Rs 2750/- per Vial

	The status in reference regulatory authorities	Gemzar Injection 200mg USFDA
	For generic drugs (me-too status)	Gemzar Injection by Eli Lilly Karachi
	Module-II (Quality Overall Summary)	Firm has submitted the QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	JARI Pharmaceutical Co., Ltd. 18 Zhenhua Road, Lianyungang City, People's Republic of China, 222006
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ℃±2. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence studies with reference product i.e. Gemzar of Eli Lilly.
	Analytical method validation/verification of product	Firm has submitted analytical method verification with Chinese Pharmacopeia Monograph.
	Container closure system of the drug product	Medium Boron Silicon Glass Tube Type Vials of 20 ml.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH. The real time stability study data of 3 batches 36months. The firm has requested for 36 months' shelf life.
Decision:	**Approved with Innovator's specifications as per Inspection Policy of manufacturers abroad for finished drugs.**	
7.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises (Pvt) Ltd., 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore**

	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24.02.2023 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Reyoung Pharmaceutical Co., Ltd., No. 1 Ruiyang Road Yiyuan County Shandong Province P.R. China
	Name, address of manufacturer(s)	M/s Reyoung Pharmaceutical Co., Ltd., No. 1 Ruiyang Road Yiyuan County Shandong Province P.R. China
	Name of exporting country	People's Republic of China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP No. 2021120005 issued by Yiyuan Market Supervision Administration of P.R China. Validity: 06.12.2023
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted b/w M/s Reyoung Pharmaceutical Co., Ltd., China and M/s AMB HK Enterprises (Pvt) Ltd. Lahore
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27482 dated 05.10.2021
	Details of fee submitted	PKR /-: 150000/- dated 07.06.2021
	The proposed proprietary name / brand name	**GLUTAYOUNG INJECTION**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Glutathione….0.6g
	Pharmaceutical form of applied drug	Lyophilized Powder for Injection
	Pharmacotherapeutic Group of (API)	Antidote (ATC Code: V03AB32)
	Reference to Finished product specifications	In-house
	Proposed Pack size	Pack of 10's Vial with 10's Ampoule WFI (5ml)
	Proposed unit price	Rs. 345/- per vail
	The status in reference regulatory authorities	Italian Medicine Agency.
	For generic drugs (me-too status)	Provided info is not traceable
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per Module II.
	Name, address of drug substance manufacturer	M/s Shandong Jincheng Zhonghu Bio- Pharmaceutical Co., Ltd Dongyi lu Xi, Fu Xian Bei, Jiaowang Road, Economic

		development Zone, Zi Chuang District Zibo City Shandong Province P.R. China
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow diagram of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 30°C ± 2°C / 75 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, method validation studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence data submitted with product of Biomedica Foscama of Italy (TAD 0.6g Injection)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I Glass Vial 5ml Type I Glass Ampoule
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 36 months Firm requested 24months shelf life
Decision:	**Deferred for following points:** • **Policy decision on the products containing glutathione keeping in view their therapeutic indications and off label uses.** • **Regulatory status of applied formulation in other reference regulatory authorities alongwith its indications, precautions, contra indications etc.**	

Agenda of Evaluator PEC-IV

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

a. New cases

	Name, address of Applicant / Marketing Authorization Holder	M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi
	Name, address of Manufacturing site.	M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30931 dated 11/11/2021
	Details of fee submitted	PKR 30,000/-: Deposit slip # 7273954379
	The proposed proprietary name / brand name	Dapazin 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin ……..5mg
	Pharmaceutical form of applied drug	Yellow color, round shape, biconvex film coated tablets, plain on both side.
	Pharmacotherapeutic Group of (API)	Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
	Reference to Finished product specifications	In-house
	Proposed Pack size	7's,10's,14's,20's,28's,30's & 60's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA 5mg tablet by ASTRAZENECA AB USA, USFDA Approved.
	For generic drugs (me-too status)	XIGA 5 mg Tablet by M/s. CCL Pharmaceutical (Pvt.) Limited, Reg. No. 090504
	GMP status of the Finished product manufacturer	GMP certificate No. 90/2020-DRAP(K) Tablet (General) section is approved.
	Name and address of API manufacturer.	M/s. Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd . Dixi street Luoyang Town, Wuin District Changzho Jiangsu China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Dapagliflozin Propanediol Monohydrate is not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A & related substances (impurity A & any unknown impurity), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (D20161001, D20161002, D20161101)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer

		medium), batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.	
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is XIGA 5mg Tablets CCL Pharmaceutical (Pvt.) Ltd by performing quality tests (Identification, Assay, Dissolution, Hardness, Disintegration Time). CDP has been performed against the same brand that is XIGA 5mg Tablets CCL Pharmaceutical (Pvt.) Ltd in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.	
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.	
STABILITY STUDY DATA			
Manufacturer of API		M/s. Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd .China	
API Lot No.		DGF20180501	
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (14's)	
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		20PD259DAPT11	20PD260DAPT12	20PD264DAPT13
Batch Size		8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date		12-2020	12-2020	12-2020
Date of Initiation		06-01-2022	06-01-2022	06-01-2022
No. of Batches		03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Apixa 2.5mg & 5mg (Apixaban) which was conducted on 30-04-2019 and was presented in 289th meeting of Registration Board held on 14th – 16th May 2019 . According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. JS20180935 issued by China Food and Drug Administration valid till 26/11/2023	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 , invoice (invoice# WIS180048) dated 05/06/2018 cleared by DRAP Karachi office dated 21.06-2018 specifying import of	

		Dapagliflozin propanediol monohydrate 1.5Kg (Batch# DGF20180501).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trial Reports are attached.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Stability chamber data (real time and accelerated) having monitoring of temperature and humidity are attached.

Remarks OF Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.5.3	In brand name 10mg mentioned. Clarification is required.	Due to typographic error,10mg was mentioned, revised document attached.
2.	3.2.P.5.3	Specifications claimed are Inhouse while drug product analytical method verification submitted. Clarification is required.	There are two strengths of Dapagliflozin Tablet, Dapagliflozin 5mg & Dapagliflozin 10mg Tablet and both formulation are with same dose proportional to excipients ratio , so analytical method validation have been performed on highest strength of Dapagliflozin 10mg Tablet. The scope have covered the Validation of analytical method in term of i.e. System Suitability, Specificity, Linearity, Precision, Intermediate, Precision Accuracy, Robustness Limit of Detection and Limit of Quantitation , hence analytical method validation of Dapagliflozin 5mg Tablet has been performed with limited parameters of analytical method validation i.e. System Suitability, Specificity, Precision.
3.	3.2.P.8	• Stability studies initiation date not mentioned on stability summary sheets. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• Revised Stability Summary sheets are attached. • Compliance record of HPLC software 21CFR & audit trial reports was submitted from Page no. 638-659, now re-submitting.

Decision: Approved with innovator's specification..

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

1099.	Name, address of Applicant / Marketing Authorization Holder	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34228 dated 31-12-2021
	Details of fee submitted	PKR 30,000/-: Deposit slip # 35283356895
	The proposed proprietary name / brand name	FOVIROX-AF Tablets 25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide … 25mg
	Pharmaceutical form of applied drug	Yellow color, circular biconvex shape film coated tablet. Both sides plain packed in HDPE Bottle of 30's tablets.
	Pharmacotherapeutic Group of (API)	Antiviral for systemic use, nucleoside and nucleotide reverse transcriptase inhibitors.
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	Packed in HDPE Bottle of 30's tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vemlidy Tablet 25mg by Gilead Sciences Ltd. U.S.A.., USFDA Approved.
	For generic drugs (me-too status)	Tenofomide Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conducted on 19-09-2020 and valid for two years.
	Name and address of API manufacturer.	M/s Yichang changJiang hec pharmaceutical Co., Ltd. No.38-62, Binjiang road ,Yidu, Hubei province P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Monograph of Tenofovir Alafenamide Fumarate is present is as per In-house (Manufacturer's) specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Impurity A, PMPA, Unspecified impurity and Total impurities), specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DTAF-151011, DTAF-151012, DTAF-151013)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tenofomide Tablets 25mg (Tenofovir Alafenamide) is registered and being marketed by Getz Pharma (Pvt.) Ltd., by performing quality tests (Description, Identification, Assay and Dissolution) CDP has been performed against the same brand that is Tenofomide Tablets 25mg (Tenofovir Alafenamide) by Getz Pharma (Pvt.) Ltd., in Acid media (pH 1.2) & Phosphate Buffer (pH 4.5 & 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Yichang changjiang hec pharmaceutical Co., Ltd. No.38-62, binjiang road ,yidu, hubei province P.R.China		
API Lot No.	TAF-201909001		
Description of Pack (Container closure system)	Packed in HDPE Bottle of 30's tablets		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	372DS01	372DS02	372DS03
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	20-09-2020	20-09-2020	20-09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HB20180453 issued by NMPA valid till 06/12/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 , invoice (invoice# SO201909240002) dated 21-10-2019 cleared by DRAP

		Karachi office dated 16-03-2020 specifying import of Tenofovir Alafenamide Fumarate 3.5Kg (Batch# TAF-201909001).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	Drug substance name in applied dossier and drug substance part is M/s Yichang changjiang hec pharmaceutical Co., Ltd while on National medical Products Administration mentioned as Yichang Dongguang changjiang pharmaceutical Co., Ltd. Clarification is required.	We would like to inform you that, the Manufacturer of said Drug substance has confirmed that, the name of Company is M/s. Yichang HEC Changjiang Pharmaceutical Co. Ltd. Having DML No. 20200013 and Social credit code: 91420000730842584f, which is also mentioned on NMPA website and as well as on attached Drug Manufacturing License, the difference in company name is due to erroneous translation from Chinese to English version on NMPA website, The Manufacturer also provided the attached undertaking for the said point on letter head, for more clarity Moreover, in 289th RB Meeting, Drug Registration board also approved the same Product (Tenofovir Alafenamide) from same API Manufacturer (M/s. Yichang HEC Changjiang Pharmaceutical Co. Ltd), extract from the said RB Meeting also attached for ready reference.

Decision: Approved with innovator's specification..

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

1100.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26029 dated 20/09/2021

	Details of fee submitted	PKR 20,000/-: Dated: 10-03-2021 Deposit slip # 2030992
	The proposed proprietary name / brand name	Metacor 500mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Metformin HCl …….500mg
	Pharmaceutical form of applied drug	White coloured oval Film coated engraved with 'W' on one side of tablet
	Pharmacotherapeutic Group of (API)	Oral Hypoglycemic agent
	Reference to Finished product specifications	BP
	Proposed Pack size	5×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glucophage 500mg tablet by M/s Martin Dow, USFDA Approved.
	For generic drugs (me-too status)	Glucophage 500mg tablet by M/s Martin Dow, Reg. No. 000552
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conducted on 08-09-2021
	Name and address of API manufacturer.	M/s AARTI DRUGS LIMITED Plot No 211 & 213, Road -2, G.I.D.C AT & Post Sarigam. City Sarigam– 396 155 Dist. Valsad Gujarat industrial estate India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Metformin Hydrochloride is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,B,C,E &F, related substances (Xyline), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Glucophage 500mg tablet by Martin Dow by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Glucophage 500mg tablet by Martin Dow in Acid media (pH-1.2),Acetate Buffer(pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s AARTI DRUGS LIMITED Plot No 211 & 213, Road -2, G.I.D.C AT & Post Sarigam. City Sarigam– 396 155 Dist. Valsad Gujarat industrial estate India.		
API Lot No.	MEF119102522		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (5×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TMR002	TMR003	TMR004
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	03-2020	05-2020	06-2020
Date of Initiation	18-07-2020	18-07-2020	18-07-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 20031933 issued by Food & Drug Control administration Gujrat state India valid till 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# EXP/1879/10-20) dated : 01-11-2019 cleared by DRAP Lahore office dated 18.11-2019 specifying import of Metformin HCl (Batch# MEF119102522).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	U.V method is used
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated).

Remarks OF Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.1	Submit Differential fee of Rs: 10000/-	Fee submitted of Rs:7500/- Deposit slip #586593611 and Rs:2500/- Deposit slip #1715662154
2.	3.2.P.5.2	• Assay method not provided. • In dissolution test complies to USP test mentioned. While claimed specifications are B.P. Clarification should be submitted in this regard.	• Assay method is attached. • Product complies to B.P specifications and it was a typographical error
3.	3.2.P.8	• As per submitted record Batch No # TMR002 was manufactured in 03-2020 while initial testing done on 11-05-2020 and samples were placed in stability chamber on 18-07-2020. Clarification is required. • Furthermore, Please justify where batch was stored before initial testing and before placement in stability chamber.	• All the three batches were placed in stability chamber together on 18-07-2020 to have simultaneous time points/intervals for stability study. But the same batch was retested on 12-07-2020 before placing in the chamber. All limits are within the limits. COA's attached. • Batch was store in controlled environment. Temperature and humidity was in limits.

Decision: Approved with BP specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

Case no. 02 Registration applications of drugs for which stability study data is submitted

b. Verification of stability study data

1101.	Name and address of manufacturer / Applicant	M/s. Weather Folds Pharmaceuticals, Plot# 69, phase-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Prolide 1mg tablet
	Composition	Each film coated tablet contains: Prucalopride as Succinate……..1mg
	Diary No. Date of R& I & fee	Dy.No 16818 dated 07-03-2019 Rs. 50,000/- 07-03-2018
	Pharmacological Group	Other drugs for constipation ATC code: A06AX05
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	MOTEGRITY of USFDA approved

	Me-too status	
	GMP status	

STABILITY STUDY DATA

Drug	Prucafold 1mg tablet		
Name of Manufacturer	M/s. Weather Folds Pharmaceuticals, Plot# 69, phase-II, Industrial Estate, Hattar.		
Manufacturer of API	M/s Kimia Biosciences Limited, (Formerly Known as Laurel Organics Limited)Village Bhondsi Tehsil-Sohna District-Gurgoan Harryana, India		
API Lot No.	KB/PPD/SSP/19/002		
Description of Pack (Container closure system)	Alu blister pack		
Stability Storage Condition	Real time : 30°C ± 2° C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.	T-61	T-62	T-63
Batch Size	1100 tablets	1100 tablets	1100 tablets
Manufacturing Date	06-2019	06-2019	06-2019
Date of Initiation	24-06-2019	24-06-2019	24-06-2019
No. of Batches	03		
Date of Submission	18-11-2020 (30716)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of Prucalopride Succinate (Batch# KB/PPD/SSP/19/002.) from M/s Kimia Biosciences Limited, India is submitted. Copy of COA of Prucalopride Succinate (Batch# KB/PPD/SSP/19/002.) from M/s. Weather Folds Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate for M/s Kimia Biosciences Limited,(Formerly Laurel Organics Ltd.) Village Bhondsi Tehsil-Sohna District-Gurgoan Haryana, India issued by Food and Drug Adminstration Haryana, Panchkula issued on 18-11-2019 and, valid for two years..
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No: KBLEXP/19-20/010 Dated: 14-03-2019 from M/s Kimia Biosciences Limited, Village Bhondsi Tehsil-

		Sohna District-Gurgoan Harryana, India attested by AD DRAP (Peshawar) dated ; 28-03-2019 for Pruclopride Succinate batch No# KB/PPD/SSP/19/002.
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	NA
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record. Details are as under: Prucafold 1mg **Batch No.** / **Bach size** / **Mfg. Started** T-61 / 1100 Tablets / 24-06-2019 T-62 / 1100 Tablets / 24-06-2019 T-63 / 1100 Tablets / 24-06-2019
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	No
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	No

- **REMARKS OF EVALUATOR**

S.NO	**Shortcoming communicated**	**Reply**
1.	Certificate of Analysis of API Finished Product manufacturer**.**	Submitted
2.	Method used for analysis of API Finished Product manufacturer	Submitted
3.	Drug-excipients compatibility studies	Excipients used in formulation of Prolide are same as of innovators
4.	Complete batch manufacturing record of three stability batches.	Submitted
5.	Record of comparative dissolution data (where applicable)	Not submitted
6.	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905> throughout stability studies. Justification shall be submitted in this regard.	Content uniformity submitted.
7.	Initiation date on Real time stability summary sheets 24-01-2019 while on	Actual date 24-06-2019, typing mistake on Real time stability summary sheets. Corrected sheets submitted.

	Accelerated stability studies 24-06-2019. Justify.	

Firm withdraw above stability data and submitted new data with new sources of API. New submitted data is as follows.

STABILITY STUDY DATA

Drug	Prucafold 1mg tablet		
Name of Manufacturer	M/s. Weather Folds Pharmaceuticals, Plot# 69, phase-II, Industrial Estate, Hattar.		
Manufacturer of API	M/s Metrochem API Private Limited. Unit-IV, Plot No. 34B, 40B & 60B, JN pharma city, Thanam (V) Parawada (M), Vishakapatnam Andhra Pradesh, India.		
API Lot No.	PCSPC20001		
Description of Pack (Container closure system)	Alu blister pack		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated:0, 3 ,6 (month) Real Time: 0,3,6 (month)		
Batch No.	T01	T02	T03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	22-04-2020	22-04-2020	22-04-2020
No. of Batches	03		
Date of Submission	17-03-2022 (7590)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of Prucalopride Succinate (Batch# PCSPC20001) from M/s Metrochem API Private Limited, India is submitted. Copy of COA of Prucalopride Succinate (Batch# PCSPC20001) from M/s. Weather Folds Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 6 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No # 1296/DD/DCA/VSP/2020 for M/s Metrochem API Private Limited. Unit-IV, Plott No. 34B, 40B & 60B, JN pharma city, Thanam (V) Parawada (M), Vishakapatnam Andhra Pradesh, India. issued by

<table>
<tr><td></td><td></td><td>Drug Control Adminstration issued on 29-09-2020 and, valid upto 28-09-2021..</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of form 3, form 7 and Commercial Invoice No: DE/19/0111 Dated: 31-01-2020 from M/s Metrochem API Private Limited. Unit-IV, Plot No. 34B, 40B & 60B, JN pharma city, Thanam (V) Parawada (M), Vishakapatnam Andhra Pradesh, India not attested for Pruclopride Succinate batch No# PCSPC20001 quantity 20grams</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>No</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>We used all excipients as per Innovator formulation hence drug excipients compatibility studies is not applicable.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:<table><tr><td colspan="3">Prucafold 1mg</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>T-01</td><td>1200 Tablets</td><td>21-04-2020</td></tr><tr><td>T-02</td><td>1200 Tablets</td><td>21-04-2020</td></tr><tr><td>T-03</td><td>1200 Tablets</td><td>21-04-2020</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Resolor”. The details are as follows:<table><tr><td>Feature</td><td>Reference product</td><td>Product of Weather fold</td></tr><tr><td>Brand name</td><td>Resolor 1mg</td><td>Prucfold 1mg Tablet</td></tr><tr><td>Batch No.</td><td>JBL2N02</td><td></td></tr></table>● Comparative dissolution studies have been performed in following mediums:
1. pH 1.2 HCl buffer
2. pH 4.5 Acetate buffer
3. pH 6.8 Phosphate buffer</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Yes</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>No</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>No</td></tr>
</table>

REMARKS OF EVALUATOR

Brand name different than for 5D file

S.No	Shortcoming communicated	Reply
1.	Submit Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer submitted.
2.	Submit Protocols followed for conduction of stability study	Specifications submitted.
3.	Submit Documents for the procurement of API with approval from DRAP	Form 6 submitted. Address of manufacturer different than COA
4.	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905>. Justification shall be submitted in this regard.	Content uniformity submitted in previous data, resubmitted.
5.	In certificate of analysis of finished products Wight variation instead of limits comply mentioned. Clarification is required.	Mistakenly written, correction were made after taking data from rough data
6.	Submit Details of CDP and details of product against which CDP conducted.	Submitted
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not available

2nd letter

Dated: 13th June, 2022

1.	Protocols followed for conduction of stability study.	Protocols followed for conduction of stability study submitted.
2.	Commercial invoice for the procurement of API with approval from DRAP not submitted.	The commercial invoice isn't attested by the concerned AD, as when we apply for import of Material for stability purpose, only Form-6 is been attested and material is also released by custom on this
3.	In Form 6 address of API manufacturer different than COA and GMP certificate. Clarification is required.	The address on form-6 was mistakenly written, it was a typographical error because Metrochem Pharma have several units and GMP. So mistakenly we mentioned Address from another GMP of Metrochem.
4.	Procurement documents for Innovator/reference product used for comparative dissolution profile	For the procurement of Innovator Reference product of CDP, we would state that it was hand carried so no procurement documents are available.

1102.	Name and address of manufacturer / Applicant	M/s. Weather Folds Pharmaceuticals, Plot# 69, phase-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Prolide 2mg tablet
	Composition	Each film coated tablet contains: Prucalopride as Succinate……..2mg
	Diary No. Date of R& I & fee	Dy.No 16819 dated 07-03-2019 Rs. 50,000/- 07-03-2018
	Pharmacological Group	Other drugs for constipation ATC code: A06AX05
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturers specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	MOTEGRITY of USFDA approved
	Me-too status	
	GMP status	

STABILITY STUDY DATA

Drug	Prucafold 2mg tablet		
Name of Manufacturer	M/s. Weather Folds Pharmaceuticals, Plot# 69, phase-II, Industrial Estate, Hattar.		
Manufacturer of API	M/s Kimia Biosciences Limited, (Formerly Known as Laurel Organics Limited)Village Bhondsi Tehsil-Sohna District-Gurgoan Harryana, India		
API Lot No.	KB/PPD/SSP/19/002		
Description of Pack (Container closure system)	Alu blister pack		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.	T-64	T-65	T-66
Batch Size	1100 tablets	1100 tablets	1100 tablets
Manufacturing Date	06-2019	06-2019	06-2019
Date of Initiation	24-06-2019	24-06-2019	24-06-2019
No. of Batches	03		
Date of Submission	18-11-2020 (30715)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of Prucalopride Succinate (Batch# KB/PPD/SSP/19/002.) from M/s Kimia Biosciences Limited, India is submitted. Copy of COA of Prucalopride Succinate (Batch# KB/PPD/SSP/19/002.) from M/s. Weather Folds Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate for M/s Kimia Biosciences Limited,(Formerly Laurel Organics Ltd.) Village Bhondsi Tehsil-Sohna District-Gurgoan Haryana, India issued by Food and Drug

		Adminstration Haryana, Panchkula issued on 18-11-2019 and, valid for two years..
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No: KBLEXP/19-20/010 Dated: 14-03-2019 from M/s Kimia Biosciences Limited, Village Bhondsi Tehsil-Sohna District-Gurgoan Harryana, India attested by AD DRAP (Peshawar) dated ; 28-03-2019 for Pruclopride Succinate batch No# KB/PPD/SSP/19/002.
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	NA
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record. Details are as under: Prucafold 2mg **Batch No.** / **Bach size** / **Mfg. Started** T-64 / 1100 Tablets / 24-06-2019 T-65 / 1100 Tablets / 24-06-2019 T-66 / 1100 Tablets / 24-06-2019
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	No
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	No

REMARKS OF EVALUATOR

S.NO	**Shortcoming communicated**	**Reply**
1.	Certificate of Analysis of API Finished Product manufacturer**.**	Submitted
2.	Method used for analysis of API Finished Product manufacturer	Submitted
3.	Drug-excipients compatibility studies	Excipients used in formulation are same as of innovators
4.	Complete batch manufacturing record of three stability batches.	Submitted
5.	Record of comparative dissolution data (where applicable)	Not submitted
6.	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter	Content uniformity submitted.

	<905> throughout stability studies. Justification shall be submitted in this regard.	
7.	Initiation date on Real time stability summary sheets 24-01-2019 while on Accelerated stability studies 24-06-2019. Justify.	Actual date 24-06-2019, typing mistake on Real time stability summary sheets. Corrected sheets submitted.

Firm withdraw above stability data and submitted new data with new sources of API. New submitted data is as follows.

STABILITY STUDY DATA

Drug	Prucafold 2mg tablet		
Name of Manufacturer	M/s. Weather Folds Pharmaceuticals, Plot# 69, phase-II, Industrial Estate, Hattar.		
Manufacturer of API	M/s Metrochem API Private Limited. Unit-IV, Plot No. 34B, 40B & 60B, JN pharma city, Thanam (V) Parawada (M), Vishakapatnam Andhra Pradesh, India.		
API Lot No.	PCSPC20001		
Description of Pack (Container closure system)	Alu blister pack		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated:0, 3 ,6 (month) Real Time: 0,3,6 (month)		
Batch No.	T04	T05	T06
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	22-04-2020	22-04-2020	22-04-2020
No. of Batches	03		
Date of Submission	17-03-2022 (7590)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of Prucalopride Succinate (Batch# PCSPC20001) from M/s Metrochem API Private Limited, India is submitted. Copy of COA of Prucalopride Succinate (Batch# PCSPC20001) from M/s. Weather Folds Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 6 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.

<table>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Copy of GMP certificate No # 1296/DD/DCA/VSP/2020 for M/s Metrochem API Private Limited. Unit-IV, Plott No. 34B, 40B & 60B, JN pharma city, Thanam (V) Parawada (M), Vishakapatnam Andhra Pradesh, India. issued by Drug Control Adminstration issued on 29-09-2020 and, valid upto 28-09-2021..</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of form 3, form 7 and Commercial Invoice No: DE/19/0111 Dated: 31-01-2020 from M/s Metrochem API Private Limited. Unit-IV, Plot No. 34B, 40B & 60B, JN pharma city, Thanam (V) Parawada (M), Vishakapatnam Andhra Pradesh, India not attested for Pruclopride Succinate batch No# PCSPC20001 quantity 20grams</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>No</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>We used all excipients as per Innovator formulation hence drug excipients compatibility studies is not applicable.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Prucafold2mg</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>T-04</td><td>1200 Tablets</td><td>21-04-2020</td></tr>
<tr><td>T-05</td><td>1200 Tablets</td><td>21-04-2020</td></tr>
<tr><td>T-06</td><td>1200 Tablets</td><td>21-04-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Resolor”. The details are as follows:
<table>
<tr><td>Feature</td><td>Reference product</td><td>Product of Weather fold</td></tr>
<tr><td>Brand name</td><td>Resolor 1mg</td><td>Prucfold 2mg Tablet</td></tr>
<tr><td>Batch No.</td><td>IELoXoo.A</td><td></td></tr>
</table>
● Comparative dissolution studies have been performed in following mediums:
1. pH 1.2 HCl buffer
2. pH 4.5 Acetate buffer
3. pH 6.8 Phosphate buffer</td></tr>
</table>

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	No
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	No

REMARKS OF EVALUATOR
Brand name different than for 5D file

S.No	Shortcomings communicated	Reply
1.	Submit Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer submitted.
2.	Submit Protocols followed for conduction of stability study	Specifications submitted.
3.	Submit Documents for the procurement of API with approval from DRAP	Form 6 submitted. Address of manufacturer different than COA
4.	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905>. Justification shall be submitted in this regard.	Content uniformity submitted in previous data, resubmitted.
5.	In certificate of analysis of finished products Wight variation instead of limits comply mentioned. Clarification is required.	Mistakenly written, correction were made after taking data from rough data
6.	Submit Details of CDP and details of product against which CDP conducted.	Submitted
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not available

2nd letter
Dated: 13th June, 2022

1.	Protocols followed for conduction of stability study.	Protocols followed for conduction of stability study submitted.
2.	Commercial invoice for the procurement of API with approval from DRAP not submitted.	The commercial invoice isn't attested by the concerned AD, as when we apply for import of Material for stability purpose, only Form-6 is been attested and material is also released by custom on this
3.	In Form 6 address of API manufacturer different than COA and GMP certificate. Clarification is required.	The address on form-6 was mistakenly written, it was a typographical error because Metrochem Pharma have several units and GMP. So mistakenly we mentioned Addres from another GMP of Metrochem.
4.	Procurement documents for Innovator/reference product used for comparative dissolution profile	For the procurement of Innovator Reference product of CDP, we would state that it was hand carried so no procurement documents are available.

Report on investigation of authenticity / genuineness of data submitted for registration of Prolide 1mg tablet (Prucalopride as Succinate) 1mg & 2mg Tablet by M/s. Weather Folds Pharmaceuticals, Plot# 69, phase-II, Industrial Estate, Hattar.

Firm Name Address: Weather folds Pharmaceutical plot No 69/2, Phase 2 Industrial Estate Hattar
Date of Inspection: **26.08.2022**

Q.No.1	Do you have documents confirming the import of Prucalopride API?	Firm provided the documents conform the import of Prucalopride API i.e. Form-6 issued by ADC dated 31-01-2020, No. F 10-72/2020-DRAP IPS 490 and attested by Assistant Director Peshawar copy attached **(Annexure 01).**
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	The firm informed that selection of API manufacturer was based upon its GMP Certification and availability of DMF (open part). The firm agreed to provide adequate sample for initial testing for prequalification. The API manufacturer qualified their vendor qualification SOP.
Q.No.3	Do you have documents confirming the import of Prucalopride reference standard and impurity standards?	Yes, the import documents of working standard, Batch No PCS-P/A069/13, Mfg. Date: Dec-2019, provided by supplier copy attached **(Annexure 02).** However, API manufacturer did not provide impurities.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Yes, certificate of Analysis of the API and working standards (Vonoprazan as fumarate) are provided. However, the API manufacturer did not provide impurities.
Q.No.5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, approval of API or GMP certificate of API manufacture METROCHEM API PVT LTD No 1296/DD/DCA/VSP/2020 valid till 28-09-2021 copy attached **(Annexure 03).**
Q.No.6	Do you use API manufacturer method of testing?	Yes, the firm use API manufacturer method of testing, also verification of API performed by the firm.
Q.No.7	Do you have stability studies reports on API?	Yes, stability studies report on API (prucalopride succinate) are provided in DMF.
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	No, the stability testing has not been performed as per SIM method and degradation product, however firm conduct stability study as per ICH guidelines.
Q.No.9	Do you have method for quantifying the impurities in the API?	Yes, the firm have API manufacturer method of testing impurities.
Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Working standard approx. 100mg available at time of inspection.
Q.No.11	Have you used pharmaceutical grade excipients?	Yes, the firm uses imported pharmaceutical grade excipient, which are procured from local suppliers. Vender qualification SOP is followed.
Q.No.12	Do you have documents confirming the import of the used excipients?	The firm purchased locally import material, COA and Evidence attached **(Annexure 04).**
Q.No.13	Do you have test reports and other records on the excipients used?	Yes, test reports and other records on the excipients use available copy attached **(Annexure 05).**

Q.No.14	Do you have written and authorized protocols for the development of Prucalopride tablets?	The firm provided written and authorized protocols for the development of Prucalopride tablet.
Q.No.15	Have you performed Drug-excipient compatibility studies?	Drug-excipient compatibility studies not performed by the firm, however Firm used brand leader formulation already studied by them copy attached **(Annexure 06).**
Q.No.16	Have you performed comparative dissolution studies?	Yes, the firm performed comparative dissolution studies in three media details attached **(Annexure 07).**
Q.No.17	Do you have product development (R&D) section	No separate dedicated product development (R&D) section is established by the firm. The firm was advised to establish R&D section with required staff on urgent basis.
Q.No.18	Do you have necessary equipments available in product development section for development of Prucalopride tablets?	Manual/ production facilities are being utilized by the firm for said purpose. The firm is committed to establish R&D section as discussed above.
Q.No.19	Are the equipments in product development section qualified?	As above.
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	As above.
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	As above.
Q.No.22	Have you manufactured three stability batches for the stability studies of Prucalopride tablets as required?	Yes the firm has manufactured three stability batches for the stability studies of Prucalopride tablets as required Prolide 1mg B.NO:T-01,T-02,T-03 Mfg date:04-2020 Exp date:04-2022, B.Size:1200 Tablet each. Prolide 2mg B.NO:T-04,T-05,T-06 Mfg date:04-2020 Exp date:04-2022 B.Size:1200 Tablet each.
Q.No.23	What was the criteria for fixing the batch size of stability batches?	The firm said that the criteria for fixing the batch size of stability batches is the number of tablets per testing frequency and number of testing frequencies while keeping in view the decision of Registration Board (RB) in its 249th Meeting.
Q.No.24	Do you have complete record of production of stability batches?	Yes batch manufacturing record available
Q.No.25	Do you have protocols for stability testing of stability batches?	Yes, firm have protocols for stability testing of stability batches as per ICH guidelines.
Q.No.26	Do you have developed and validated the method for testing of stability batches?	Yes, the firm has developed and validated the method for testing of stability batches summary report attached **(Annexure 08).**

Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	NA
Q.No.28	Do you have documents confirming the qualification of Equipments / instruments being used in the test and analysis of Prucalopride API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug.
Q.No.29	Do your method of analysis stability indicate?	Degradation study not performed by firm
Q.No.30	Do your HPLC software is 21CFR compliant?	Water 600 pump 486 Detector Empower 2 software 21 CFR Complies
Q.No.31	Can you show Audit Trail reports on Prucalopride testing?	Audit trail on the testing reports is fully available.
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	Only Stability batches available
Q.No.33	Do you have commitment batches kept on stability testing?	Yes
Q.No.34	Do you have valid calibration status for the Equipments used in Prucalopride tablets production in analysis?	The firm has valid calibration status for the equipment used in production and analysis of Prucalopride **(Annexure 09)**
Q.No.35	Do proper and continuous monitoring and control are available for stability chamber?	digital record of chamber available, Binder chamber 21CFR Complies with ups backup and generator available
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are in compliance
Q.No.36	Power supply Backup	Separate generator available for both QC and Production. Start within minute after light breakage 100KW for Production 25KW for QC Department

With reference to queries, reply is placed at S. No. 1&3. Based on physical inspection and data reviewed, panel has verified the stability data provided by the firm.

Decision:

- **Registration Board decided to approve registration of Prolide 1mg Tablet (Prucalopride as Succinate) and Prolide 2mg Tablet (Prucalopride as Succinate) with Innovator's specifications by M/s. Weather Folds Pharmaceuticals. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**
- **Firm shall submit the fee of Rs. 75,000/- for submission of new stability data, for both products separately as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

Agenda of Evaluator PEC-XIV

Case No. Registration applications of local manufacturing of human drugs submitted on CTD format (New License)

On the recommendations of panel of experts, the CLB in its 276th meeting held on 03rd September, 2020 has considered and approved the grant of Drug Manufacturing License in the name of M/s Alpenglow pharmaceuticals (Pvt) Ltd, Plot No. A7, Risalpur Export processing Zone, Risalpur.

v. Capsule (Cephalosporin) (1 molecule / 2products)
vi. Dry Powder injection section (Cephalosporin) (1 molecule / 7 products)
vii. Dry powder suspension section (Cephalosporin) (1 molecule / 2 products)
viii. Tablet (Psychotropic)

New cases:

1103.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5855: Dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	BACCIL 200mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime as trihydrate…….200 mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, Third-generation cephalosporins
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1 x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Cefixima Norman 200mg** (AEMPS Approved).
	For generic drugs (me-too status)	Cefim 200 mg Capsule
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Pharmagen Ltd., Address: Kot nabi Bukhsh wala, 34-Km Ferozepur Road, Lahore-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefixime as trihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C±2°C / 65% ± 5%RH for 72 months Accelerated: 40°C±2°C / 75% ± 5%RH for 6 months Batches: (120512013, 120512014, 120512015)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product that is Cefim 200 mg Capsule by Hilton Pharma by performing quality tests (Identification, assay, Dissolution, Uniformity of dosage form). CDP has been performed against the comparator product that is Cefim 200 mg Capsule by Hilton Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision and specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Ltd., Address: Kot nabi Bukhsh wala, 34-Km Ferozepur Road, Lahore-Pakistan.
API Lot No.	00244-05/095/2021
Description of Pack (Container closure system)	Blister pack of 5's, Printed Unit Carton**,** Product Insert
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 2, 4, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	004	005	006
Batch Size	10000 Capsules	10000 Capsules	10000 Capsules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	14-06-2021	14-06-2021	14-06-2021
No. of Batches	03		

DOCUMENTS /DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted GMP certificate (06/2019-DRAP(AD/607409-530) issued by DRAP, Lahore dated 11-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase Cefixime (compacted, Batch # 00244-05/095/2021, 25kg) from M/s pharmagen limited, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	As our pharma is new licensee, and we have not came into production. Now we have HPLC (Shimadzu 10AT) which is not 21CFR compliance. However, we commit that we will soon perform the stability studies on a 21CFR compliance HPLC system.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) was submitted.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	In form 5F, USP specs has been mentioned for product, however monograph do not exist in USP, justify.	In USP, the monograph of cefixime tablet exists, the method of analysis of cefixime tablet was used for the cefixime capsule, so USP specs were claimed. However, after the decision of DRAP the product was tested as per specifications defined in 313 meeting of registration board (notification No. F.14-1/2022-PEC) and the results were in concordant to specifications. So it is requested to the board to approved the product as per specifications of cefixime capsule defined in 313 RB meeting of DRAP.
2.	Copies of the Drug Substance Specifications and Analytical procedures used for routine testing of the drug substance / Active Pharmaceutical Ingredient by both Drug Substance & Drug Product Manufacturer are required.	Submitted.
3.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug Product Manufacturer for both compendia as well as non-compendial drug substance shall be submitted.	The firm has submitted method verification studies for assay testing of cefixime using system suitability, accuracy, precision, and specificity.

4.	The assay Limit Specified by the drug substance manufacturer (95% to 102%) is different from that specified by drug product manufacturer (95% to 103%) Justification is required.	As per USP, the assay limit of cefixime trihydrate is 95% to 103%. The specification in CoA was incorrect and revised CoA as per USP is submitted.
5.	The submitted CoA shows that the material is of micronised nature. Justify	Mistakenly the CoA of suspension was submitted. The material used in capsule is of compacted nature. The relevant CoA is submitted.
6.	Provide COA of reference standard which is actually used in analysis of drug substance	The firm has submitted CoA of USP reference standard.
7.	Submit Master Formulation including Theoretical fill weight per unit.	The firm has submitted qualitative and quantitative master formulation including theoretical fill weight per capsule.
8.	Justify why the pharmaceutical equivalence was not performed with the innovator's product.	As cefixime capsule is a generic drug product and for the reason of unavailability of innovator's pack due to pandemic COVID, the equivalence studies were performed with a DRAP registered competitor's brand.
9.	Analytical procedure of cephradine capsule has been given in relevant section instead of cefixime capsule.	The analytical procedure was misplaced with cephradine dossier. The method of analysis of cefixime capsule as per DRAP notification was used.
10.	Provide standard and sample preparation methods used in analytical method verification studies. Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	The firm has submitted method verification for assay of drug product using system, accuracy, precision, and specificity.
11.	Test method for Cefixime as trihydrate Tablet is provided in analytical method verification studies while applied formulation is Cefixime capsule.	The analytical procedure of cefixime tablet dossier was mistakenly mixed with capsule dossier while compiling. The cefixime capsule method was used for testing and verification of method is given above.
12.	The Peak area of standard solution concentration in analytical method verification studies is approximately 6609294 while the peak area of the standard solution of same concentration in stability studies is 5344596. Clarify the difference in peak areas.	The actual area is near about 5280920. The area difference is because of difference in injection volume. The method was verified with actual injection volume and detailed report of verification study of capsule is provided
13.	The result of batch analysis and stability data reflect that dissolution test has not been performed throughout the stability studies. Justify?	The dissolution test was performed at each interval of accelerated and real time stability study. FDA dissolution parameters were adopted and all the results were found within the specified limit.
14.	Justify the addition of test of pH in stability studies of cefixime capsule.	pH test was performed as an internal test. The pH test was performed by same method as that of cefixime raw material.
15.	Provide raw data sheets to justify the calculation of the results for assay testing.	Not submitted
16.	Submit copy of commercial invoice for evidence of purchase of drug substance that have been used in the development of analysis of each batch of Drug Product	The firm has submitted copy of invoice for the purchase Cefixime (compacted, Batch # 00244-05/095/2021, 25kg) from M/s pharmagen limited, Lahore.
17.	Submit Compliance record of HPLC Software 21 CFR and Audit trail report on product testing.	As our pharma is new licensee, and we have not came into production. Now we have HPLC (Shimadzu 10AT) which is not 21CFR compliance. However, we commit that we will

		soon perform the stability studies on a 21CFR compliance HPLC system.

Decision: Approved with Manufacturer's Specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1104.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.5856 Dated 03-03-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	BACCIL 400mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime as trihydrate…….400 mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1 x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX ® (cefixime) capsules, 400 mg (USFDA Approved).
	For generic drugs (me-too status)	Cefim 400 mg Capsule of M/s Hilton Pharma
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Pharmagen Pvt. Ltd., Address: Kot nabi Bukhsh wala, 34-Km Ferozepur Road, Lahore Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and

		its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefixime as Trihydrate is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (120512013, 120512014, 120512015).
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product that is Cefim 400 mg Capsule (Batch # 137989) by Hilton Pharma by performing quality tests (Identification, assay, dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is is Cefim 400 mg Capsule by Hilton Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f_1 and f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Ltd.,		
API Lot No.	00243-08/160-2021		
Description of Pack (Container closure system)	Blister pack of 5's, Printed Unit Carton**,** Product Insert		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003

Batch Size	10000 Capsules	10000 Capsules	10000 Capsules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	14-06-2021	14-06-2021	14-06-2021
No. of Batches	03		

DOCUMENTS /DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted GMP certificate (06/2019-DRAP(AD/607409-530) issued by DRAP, Lahore dated 11-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase Cefixime (compacted, Batch # 00244-05/095/2021, 25kg) from M/s pharmagen limited, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	As our pharma is new licensee, and we have not came into production. Now we have HPLC (Shimadzu 10AT) which is not 21CFR compliance. However, we commit that we will soon perform the stability studies on a 21CFR compliance HPLC system.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) was submitted.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	In form 5F, USP specs has been mentioned for product, however monograph do not exist in USP, justify.	In USP, the monograph of cefixime tablet exists, the method of analysis of cefixime tablet was used for the cefixime capsule, so USP specs were claimed. However, after the decision of DRAP the product was tested as per specifications defined in 313 meeting of registration board (notification No. F.14-1/2022-PEC) and the results were in concordant to specifications. So it is requested to the board to approved the product as per specifications of cefixime capsule defined in 313 RB meeting of DRAP.
2.	Copies of the Drug Substance Specifications and Analytical procedures used for routine testing of the drug substance / Active Pharmaceutical Ingredient by both Drug Substance & Drug Product Manufacturer are required.	Submitted.
3.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug Product Manufacturer for both compendia as well as non-compendial drug substance shall be submitted.	The firm has submitted method verification studies for assay testing of cefixime using system suitability, accuracy, precision, and specificity.
4.	The assay Limit Specified by the drug substance manufacturer (95% to 102%) is different from	As per USP, the assay limit of cefixime trihydrate is 95% to 103%. The specification in

	that specified by drug product manufacturer (95% to 103%) Justification is required.	CoA was incorrect and revised CoA as per USP is submitted.
5.	The submitted CoA shows that the material is of micronised nature. Justify	Mistakenly the CoA of suspension was submitted. The material used in capsule is of compacted nature. The relevant CoA is submitted.
6.	Provide COA of reference standard which is actually used in analysis of drug substance	The firm has submitted CoA of USP reference standard.
7.	Submit Master Formulation including Theoretical fill weight per unit.	The firm has submitted qualitative and quantitative master formulation including theoretical fill weight per capsule.
8.	Justify why the pharmaceutical equivalence was not performed with the innovator's product.	As cefixime capsule is a generic drug product and for the reason of unavailability of innovator's pack due to pandemic COVID, the equivalence studies were performed with a DRAP registered competitor's brand.
9.	Analytical procedure of cephradine capsule has been given in relevant section instead of cefixime capsule.	The analytical procedure was misplaced with cephradine dossier. The method of analysis of cefixime capsule as per DRAP notification was used.
10.	Provide standard and sample preparation methods used in analytical method verification studies. Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	The firm has submitted method verification for assay of drug product using system, accuracy, precision, and specificity.
11.	Test method for Cefixime as trihydrate Tablet is provided in analytical method verification studies while applied formulation is Cefixime capsule.	The analytical procedure of cefixime tablet dossier was mistakenly mixed with capsule dossier while compiling. The cefixime capsule method was used for testing and verification of method is given above.
12.	The Peak area of standard solution concentration in analytical method verification studies is approximately 6609294 while the peak area of the standard solution of same concentration in stability studies is 5344596. Clarify the difference in peak areas.	The actual area is near about 5280920. The area difference is because of difference in injection volume. The method was verified with actual injection volume and detailed report of verification study of capsule is provided
13.	The result of batch analysis and stability data reflect that dissolution test has not been performed throughout the stability studies. Justify?	The dissolution test was performed at each interval of accelerated and real time stability study. FDA dissolution parameters were adopted and all the results were found within the specified limit.
14.	Justify the addition of test of pH in stability studies of cefixime capsule.	pH test was performed as an internal test. The pH test was performed by same method as that of cefixime raw material.
15.	Provide raw data sheets to justify the calculation of the results for assay testing.	Not submitted
16.	Submit copy of commercial invoice for evidence of purchase of drug substance that have been used in the development of analysis of each batch of Drug Product	The firm has submitted copy of invoice for the purchase Cefixime (compacted, Batch # 00244-05/095/2021, 25kg) from M/s pharmagen limited, Lahore.
17.	Submit Compliance record of HPLC Software 21 CFR and Audit trail report on product testing.	As our pharma is new licensee, and we have not came into production. Now we have HPLC (Shimadzu 10AT) which is not 21CFR compliance. However, we commit that we will soon perform the stability studies on a 21CFR compliance HPLC system.

Decision: Approved with Manufacturer's Specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Firm will submit data of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product i.e. Cefspan 400mg Capsule before issuance of Registration letter.**

Case No. Registration applications of local manufacturing of human drugs submitted on CTD format (New License)
M/s Alpenglow pharmaceuticals (Pvt) Ltd, Plot No. A7, Risalpur Export Processing Zone, Risalpur.

Deferred cases:

1105.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of Application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5229 Dated 24-02-2022
	Details of fee submitted	PKR 30,000/-: Dated 20-10-2021
	The proposed proprietary name / brand name	BACCIL Suspension 100 mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml after reconstitution contains Cefixime as trihydrate……100 mg
	Pharmaceutical form of applied drug	Granules for Oral Suspension
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX ® (cefixime) for oral suspension, 100 mg/5 mL (USFDA Approved)
	For generic drugs (me-too status)	Caricef Suspension 100mg/5ml 30ml

	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Pharmagen Pvt. Limited, Address: Kot Nabi Bukhsh wala, 34-Km Ferozepur Road, Lahore Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefixime as Trihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C±2˚C/65%±5%RH for 72 months Accelerated:40˚C±2˚C/75%±5%RH for 6 months Batches: (120512013, 120512014, 120512015)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	N/A
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Pvt. Limited., Address: Kot Nabi Bukhsh wala, 34-Km Ferozepur Road, Lahore Pakistan
API Lot No.	00243-08/160-2021
Description of pack (Container closure system)	30ml HDPE Bottle with embossed board unit carton UV coated. (1's)
Stability storage condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch size	2000 Bottles	2000 Bottles	2000 Bottles
Manufacturing Date	06-2021	06-2021	06-2021
Date of initiation	15-06-2021	15-06-2021	15-06-2021
No. of Batches	03		

DOCUMENTS /DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note dated 16-08-2021 specifying purchase of 25Kg Cefixime (micronised).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	Copies of the Drug Substance Specifications and Analytical procedures used for routine testing of the drug substance / active Pharmaceutical Ingredient by both Drug Substance & Drug Product Manufacturer are required.	The firm has submitted copies of drug substance specifications and analytical procedures from both drug substance manufacturer and drug product manufacturer.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Analytical method verification studies were submitted from drug product manufacturer by performing specificity, accuracy and precision studies.
3.	• The assay limit specified by drug substance manufacturer (95% to 102) is different from that specified by drug product manufacturer (95% to 103%). Justification is required. • The submitted COA shows that the material used is of compacted nature. Justify the type of drug substance used in cefixime suspension since the same is used in Capsule dosage form.	As per USP, the assay limit of cefixime trihydrate is 95% to 103%. The specification in CoA was incorrect and revised CoA as per USP is attached. Mistakenly the CoA of Capsule was submitted. The material used in dry suspension is of micronized nature. The relevant COA is attached.
4.	Provide COA of reference standard which is actually used in the analysis of drug substance	The firm has submitted USP reference standard with lot no. G01139.
5.	Submit master formulation including theoretical fill weight per bottle.	The firm has submitted qualitative and quantitative formula alongwith calculation of equivalency factor of cefixime trihydrate.
6.	• Details of applicant and reference product used in pharmaceutical equivalence are required.	The firm has used cefiget 100mg/5ml dry suspension as reference product. *However,*

	• Submit data of compatibility studies of the drug product with recommended diluent in section 3.2.P.2.6.	*details of reference product including batch number, manufacturing date and expiry date were not provided.* Compatibility studies were conducted using purified water since the label recommends reconstituting this product with purified water.
7.	• The developed formulation is available in 30ml bottle, while the innovator product is available in 50ml, 75ml and 100ml bottle size only. Justify how your formulation will deliver equal number of doses as delivered by the innovator product. • Justify why drug release studies / comparative dissolution studies were not performed to justify your formulation development process	*The submitted justification is not relevant to the point raised.* As the cefixime suspension is formulated as per USP specifications, and USP does not define the test for dissolution of product, so the dissolution is not considered in specification of finished product. However, in the process of formulation development, comparative dissolution was performed in three different media following the parameters defined in FDA dissolution guidelines. Comparative study report is attached.
8.	• The test for deliverable volume is not added in specifications as recommended in USP monograph. Revise your specifications as per USP monograph along with submission of applicable fee. • Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing copy of USP monograph.	The firm has included the test for deliverable volume after reconstitution and revised specifications of finished product are submitted. Detailed method of analysis of the drug product is provided.
9.	• Provide standard and sample preparation methods used in analytical method verification studies. • Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions. • Test method for Cefixime as trihydrate Tablet is provided in analytical method verification studies while applied formulation is cefixime as trihydrate suspension. • The peak area of standard solution concentration in analytical method verification studies is approximately 6609294 while the peak area of the standard solution of same concentration in stability studies is 516942. Clarify the difference in peak areas.	Not submitted. The firm has submitted method verification of drug product by performing accuracy, precision and specificity parameters. *Details of concentrations of 80%, 100% and 120% were not provided.* Method verification report of drug product is attached. The actual area is near about 516942. The area of approx. 6609294 is that of method verification of cefixime capsule. *Mistakenly the area of verification study of capsule was mixed with suspension.*
10.	Provide COA of reference standard actually used in the analysis of drug product.	USP reference standard of cefixime with lot no. G01139 has been submitted.
11.	In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	As defined in the labelling, the in-use stability was tested by keeping the reconstituted suspension at room temperature for 7 days and in refrigerator for 14 days.
12.	• USP monograph specifies that the retention time should be 10 minutes, while the retention time in your submitted results is less than 10	USP defines that the flow rate should be adjusted that the retention time is about 10 min. Our retention is a few seconds less than 10 min which is in the acceptable range.

	min. Justify how the method can be considered as per USP monograph.	
13.	Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch.	Not submitted
14.	Submit copy of commercial invoice for evidence of purchase of drug substance that have been used in the development of analysis of each batch of drug product.	The firm has submitted copy of delivery note from M/s pharmagen limited stating purchase of Cefixime micronized 25kg. *However, purchase invoice is not submitted.*
15.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	As our pharma is a new licensee, and we have not come into production. Now we have HPLC (Shimadzu 10AT) which is not 21CFR compliance. However, we commit that we will soon perform the stability studies on a 21CFR compliance HPLC system.

Previous Decision: 317 meeting

Sr. No.	**Decision of 317th meeting**	**Response by the firm**
1.	Performance of pharmaceutical equivalence and CDP studies with innovator/reference product i.e., Cefspan 100mg / 5ml Dry suspension.	Firm has submitted pharmaceutical equivalence and CDP along with Cefspan 100mg/5ml suspension.
2.	Details of reference product including batch number, manufacturing date and expiry date.	Batch Number: D2159 Manufacturing Date: 07-2022 Expiry Date: 06-2024
3.	Analytical method verification reports of drug product including standard and sample preparation methods used in each tested parameter.	Firm has submitted report of verification studies of analytical method of drug product.
4.	Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch.	Firm has submitted raw data sheets for calculation of results for assay testing at each time point during the stability testing of each batch.

Decision: Approved.

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

1106.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. dated 24/02/2022
	Details of fee submitted	PKR 30,000/-: dated 20/10/2021

	The proposed proprietary name / brand name	Baccil Suspension 200 mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml after reconstitution contains: Cefixime as trihydrate……200 mg
	Pharmaceutical form of applied drug	Dry Powder Granules for Oral Suspension
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX ® (cefixime) for oral suspension, 200 mg/5 mL (USFDA Approved).
	For generic drugs (me-too status)	Caricef Suspension 200mg/5ml 30ml
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Pharmagen Pvt. Limited., Address: Kot nabi Bukhsh wala,34-KM Ferozepur Road, Lahore Pakistan Tel: 04235761434-35751093
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefixime trihydrate is present in USP. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (120512013, 120512014, 120512015)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	N/A.

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/S Pharmagen Pvt. LTD		
API Lot No.	00243-08/160-2021		
Description of Pack (Container closure system)	30ml HDPE Bottle with embossed board unit carton UV coated (1's).		
Stability Storage condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	004	005	006
Batch Size	2000 Bottles	2000 Bottles	2000 Bottles
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	15-06-2021	15-06-2021	15-06-2021
No. of Batches	03		

DOCUMENTS/DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivry note dated 16-08-2021 specifying purchase of 25Kg Cefixime (micronised).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr. No.	**Observations**	**Response by the firm**
1.	Copies of the Drug Substance Specifications and Analytical procedures used for routine testing of the drug substance / active Pharmaceutical Ingredient by both Drug Substance & Drug Product Manufacturer are required.	The firm has submitted copies of drug substance specifications and analytical procedures from both drug substance manufacturer and drug product manufacturer.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Analytical method verification studies were submitted from drug product manufacturer by performing specificity, accuracy and precision studies.

3.	• The assay limit specified by drug substance manufacturer (95% to 102) is different from that specified by drug product manufacturer (95% to 103%). Justification is required. • The submitted COA shows that the material used is of compacted nature. Justify the type of drug substance used in cefixime suspension since the same is used in Capsule dosage form.	As per USP, the assay limit of cefixime trihydrate is 95% to 103%. The specification in CoA was incorrect and revised CoA as per USP is attached. Mistakenly the CoA of Capsule was submitted. The material used in dry suspension is of micronized nature. The relevant COA is attached.
4.	Provide COA of reference standard which is actually used in the analysis of drug substance	The firm has submitted USP reference standard with lot no. G01139.
5.	Submit master formulation including theoretical fill weight per bottle.	The firm has submitted qualitative and quantitative formula alongwith calculation of equivalency factor of cefixime trihydrate.
6.	• Details of applicant and reference product used in pharmaceutical equivalence are required. • Submit data of compatibility studies of the drug product with recommended diluent in section 3.2.P.2.6.	The firm has used cefiget 100mg/5ml dry suspension as reference product. *However, details of reference product including batch number, manufacturing date and expiry date were not provided.* Compatibility studies were conducted using purified water since the label recommends reconstituting this product with purified water.
7.	• The developed formulation is available in 30ml bottle, while the innovator product is available in 50ml, 75ml and 100ml bottle size only. Justify how your formulation will deliver equal number of doses as delivered by the innovator product. • Justify why drug release studies / comparative dissolution studies were not performed to justify your formulation development process	*The submitted justification is not relevant to the point raised.* As the cefixime suspension is formulated as per USP specifications, and USP does not define the test for dissolution of product, so the dissolution is not considered in specification of finished product. However, in the process of formulation development, comparative dissolution was performed in three different media following the parameters defined in FDA dissolution guidelines. Comparative study report is attached.
8.	• The test for deliverable volume is not added in specifications as recommended in USP monograph. Revise your specifications as per USP monograph along with submission of applicable fee. • Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing copy of USP monograph.	The firm has included the test for deliverable volume after reconstitution and revised specifications of finished product are submitted. Detailed method of analysis of the drug product is provided.

9.	• Provide standard and sample preparation methods used in analytical method verification studies. • Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions. • Test method for Cefixime as trihydrate Tablet is provided in analytical method verification studies while applied formulation is cefixime as trihydrate suspension. • The peak area of standard solution concentration in analytical method verification studies is approximately 6609294 while the peak area of the standard solution of same concentration in stability studies is 516942. Clarify the difference in peak areas.	Not submitted. The firm has submitted method verification of drug product by performing accuracy, precision and specificity parameters. *Details of concentrations of 80%, 100% and 120% were not provided.* Method verification report of drug product is attached. The actual area is near about 516942. The area of approx. 6609294 is that of method verification of cefixime capsule. *Mistakenly the area of verification study of capsule was mixed with suspension.*
10.	Provide COA of reference standard actually used in the analysis of drug product.	USP reference standard of cefixime with lot no. G01139 has been submitted.
11.	In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	As defined in the labelling, the in-use stability was tested by keeping the reconstituted suspension at room temperature for 7 days and in refrigerator for 14 days.
12.	• USP monograph specifies that the retention time should be 10 minutes, while the retention time in your submitted results is less than 10 min. Justify how the method can be considered as per USP monograph.	USP defines that the flow rate should be adjusted that the retention time is about 10 min. Our retention is a few seconds less than 10 min which is in the acceptable range.
13.	Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch.	Not submitted
14.	Submit copy of commercial invoice for evidence of purchase of drug substance that have been used in the development of analysis of each batch of drug product.	The firm has submitted copy of delivery note from M/s pharmagen limited stating purchase of Cefixime micronized 25kg. *However, purchase invoice is not submitted.*
15.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	As our pharma is a new licensee, and we have not come into production. Now we have HPLC (Shimadzu 10AT) which is not 21CFR compliance. However, we commit that we will soon perform the stability studies on a 21CFR compliance HPLC system.

Previous Decision: 317 meeting

Sr. No.	**Decision of 317th meeting**	**Response by the firm**
1.	Performance of pharmaceutical equivalence and CDP studies with innovator/reference product i.e., Cefspan 100mg / 5ml Dry suspension.	Firm has submitted pharmaceutical equivalence and CDP along with Cefspan 200mg/5ml suspension.
2.	Details of reference product including batch number, manufacturing date and expiry date.	Reference product: Cefspan 200mg/5mL Suspension Batch Number: D1181 Manufacturing Date: 05-2022 Expiry Date: 04-2024
3.	Analytical method verification reports of drug product including standard and sample preparation methods used in each tested parameter.	Firm has submitted report of verification studies of analytical method of drug product.

4.	Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch.	Firm has submitted raw data sheets for calculation of results for assay testing at each time point during the stability testing of each batch.

Decision: Approved.

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

Registration applications of local manufacturing of human drugs submitted on CTD format

b. New Cases

1107.	Name, address of Applicant / Marketing Authorization Holder	M/s Genome Pharmaceutical (Pvt.) Ltd., Address: 16/I, Phase IV, Industrial Estate Hattar, KPK, Pakistan
	Name, address of Manufacturing site.	M/s Genome Pharmaceutical (Pvt.) Ltd., Address: 16/I, Phase IV, Industrial Estate Hattar, KPK, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25923 Dated 17-09-2021
	Details of fee submitted	PKR 75,000/-: Dated 01-09-2021
	The proposed proprietary name / brand name	Cagoline 0.5 mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet contains: Cabergoline……0.5mg
	Pharmaceutical form of applied drug	White to Off white, round, biconvex, unscored, uncoated tablets
	Pharmacotherapeutic Group of (API)	Prolactin inhibitors; ATC Code: G02CB03
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1x 10's, 1 x 20's, 1x 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dostinex 0.5 mg Tablet by Pfizer Inc, Italya, (USFDA approved).
	For generic drugs (me-too status)	N.A
	GMP status of the Finished product manufacturer	The firm is issued GMP certificate based upon inspection conducted on 26-06-2020.
	Name and address of API manufacturer.	M/s Alven Laboratories S.R.O. Šlechtitelů 813/21, Holice, 779 00 Olomouc 9, Czech Republic.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Stability studies	Stability study conditions: Real time: 30°C±2°C / 65% ± 5%RH for 72 months Accelerated: 40°C±2°C / 75% ± 5%RH for 6 months Batches: (001082016, 002082016, 003082016)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the reference is Dostinex 0.5 mg Tablet by Pfizer Inc, Italya (Batch # DA2743) by performing quality tests (Identification, Assay, Dissolution, and Disintegration time). CDP has been performed against the same reference product in three media; Acid media (pH 1.2), Acetate (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies of drug product have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Alven Laboratories S.R.O. **Address:** Šlechtitelů 813/21, Holice, 779 00 Olomouc 9, Czech Republic.
API Lot No.	001012020
Description of Pack (Container closure system)	Primary Container: 10 tablets are packed in Alu-Alu Foil Secondary Container: 1 blister of Alu-Alu Foil containing 10 film-coated tablets, packed in a printed carton along with a leaflet.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	CAB-T001	CAB-T002	CAB-T003
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	11-07-2020	14-07-2020	16-07-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to onsite inspection report of their product "Valsac 24mg/26 mg Tablets, Valsac 49mg/51 mg Tablets, Valsac 97mg/103 mg Tablets"which was conducted on 10-03-2020, and was presented in 295th meeting of Registration Board (8-11 June, 2020). Following observations were reported in the report: • The HPLC software is 21CFR Compliant. • Audit trail reports were available and physically checked. Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP for Alven Laboratories issued by the competent authority of Czeshia certificate no. *sukls* 94375/2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice (invoice# 20.60070) cleared by DRAP Peshawar Office, Pakistan dated 21-05-2020 specifying import 0.01 kg of cabergoline (Batch# 001012020).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:
DOSTINEX tablets are indicated for the treatment of hyper-prolactinemic disorders, either idiopathic or due to pituitary adenomas.

Sr. No.	Observations	Response by the firm
1.	Submit valid copy of GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin.	The firm has submitted copy of Eudra GMP for M/s Alven Laboratories s.r.o. issued by the competent authority of Czeshia certificate no. *sukls* 94375/2019. It is valid till 25-01-2024.
2.	Clarify why you have tested a Ph. Eur grade drug substance by applying USP monograph since many tests are not included in USP 43.	As the drug substance and drug product monographs are available in USP, therefore all the tests are performed according to USP monograph for both drug substances and drug product as per drug specification Rules.
3.	Justify the addition of tests of weight of tablet and disintegration time in stability studies since the same is not included in	In stability studies, all the parameters are tested mentioned in general monograph of Tablets. The tests of uniformity of weight and disintegration tests are given in the general monograph of film

	pharmacopoeia instead pharmacopoeia recommends test of uniformity of dosage unit.	coated tablets of USP. The disintegration test is variable parameter that can be affected during stability studies and therefore disintegration test is included to monitor the changes during stability studies.
4.	Submit documents of the procurement of API with approval from DRAP.	The firm has submitted copy of invoice for the purchase of Cabergoline (10g, 001012020) attested by Assistant Director (I & E), DRAP peshawar dated 21-05-2020.
5.	Submit compliance record of HPLC software 21 CFR and audit trail reports on product testing.	The firm has submitted audit trail reports on product testing.

Decision: Approved.

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

1108.	Name, address of Applicant / Marketing Authorization Holder	M/s Relizon Pharmaceuticals, Plot No. 118, Sundar industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Relizon Pharmaceuticals, Plot No. 118, Sundar industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23865 Dated 31-08-2020
	Details of fee submitted	PKR 20,000/-: Dated 04-01-2021 PKR 10,000/- Dated 28-07-2021
	The proposed proprietary name / brand name	Dexon 30mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Dexlansoprazole DDR Pellets eq. to Dexlansoprazole…….30mg
	Pharmaceutical form of applied drug	White to grayish-white colored granular pellets filled in empty capsule shell # 3 (Blue Cap and Transparent Body) Alu Alu Pack in Carton
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	3 × 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 30mg Capsule by M/s Takeda Pharms USA, (USFDA Approved).
	For generic drugs (me-too status)	Dexiva 30mg Capsule by M/s Ferozsons Laboratories, Reg. No. 091333
	GMP status of the Finished product manufacturer	New license granted on 19-03-2022. Tablet (General) Capsule (General)

		Dry Powder suspension (General)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Islamabad.
	Module-II (Quality Overall Summary)	Relizon Pharma has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Dexlansoprazole Pellets is not present in pharmacopoeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C±2°C/ 65% ± 5%RH for 72 months Accelerated: 40°C±2°C/ 75% ± 5%RH for 6 months Batches: (DLP123T, DLP124T, DLP125T)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Dexiva 30mg Capsule (Batch # 039C47) by M/s Ferozsons Laboratories by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same product that is Dexon 30mg capsule by M/s Relizon Pharma in Acid media (pH 0.1N HCl) & Phosphate Buffer (pH 5.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vision Pharmaceuticals Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Islamabad. Pakistan.
API Lot No.	DLP467

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST-001	ST-002	ST-003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	23-09-2019	24-09-2019	26-09-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Applicant has submitted GMP certificate having following information on it: Certificate No. F.3-26/2019-Addl. Dir. (QA&LT-1) Issued to: M/s. Vision Pharmaceuticals Validity: 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of Delivery challan for the purchase of Dexlansoprazole DDR pellets 22.5% (quantity 2.5 kg) from M/s. Vision Pharmaceuticals, Islamabad which is a local source.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has not submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has not submitted any document.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
6.	You have claimed USP specification in module 1 while the product monograph is not present in available monograph.	This is a typographical mistake. The product monograph is in-house.
7.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method validation of the test method for the determination of Dexlansoprazole 22.5% DDR pellets by performing specificity, linearity, accuracy, intermediate precision, repeatability and robustness.
8.	Justify why pharmaceutical equivalence and CDP studies were not performed against innovator product (Dexilant).	We use Dexiva capsule for pharmaceutical equivalence and CDP studies since this brand is easily available in market.
9.	Justify why pharmaceutical equivalence study does not include complete testing of the drug	Not submitted.

	product and the comparator product including the tests recommended by innovator product.	
10.	Clarify the type of capsule shell used in dexlansoprazole pellets since innovator product has specified hypromellose capsule shells.	We use hard gelatin capsule for the filling of Dexon Capsule.
11.	If the product monograph is present in USP, justify how you have adopted specifications and analytical procedures of drug substance manufacturer.	The product is not available in USP, so we use in-house method.
12.	The tests of content uniformity and loss on drying were not included in the submitted specifications as recommended by literature of innovator product.	Not submitted
13.	Submit analytical procedures of all the tests mentioned in finished drug product specifications.	The firm has submitted analytical procedures used for testing of drug product.
14.	Justify analytical method for assay testing without performance of analytical method verification / validation studies. Justify your statement that since the product is pharmacopoeial therefore analytical process validation is not mandatory in the light of Pharmacopoeial/ICH/WHO guidelines.	The firm has not submitted analytical method validation studies of drug product.
15.	The results of batch analysis and stability data reflect that tests of content uniformity and loss on drying have not been performed throughout stability studies. Justify your stability study data without performance of these tests.	Not submitted.
16.	Justify the selection of time points for stability studies in the light of relevant guidelines.	Not submitted.
17.	Submit copy of invoice for evidence of purchase of pellets used in the development of analysis of each batch of drug product.	The firm has submitted copy of invoice (600714) for the purchase of Dexlansoprazole DDR pellets 22.5% (batch # DLP467, 3kg) dated 12-09-2019.
18.	Provide copy of Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Not submitted
19.	Submit copy of GMP certificate of drug substance manufacturer.	The firm has submitted copy of GMP certificate for M/s Vision Pharmaceuticals issued by Additional Director, DRAP, Islamabad. The certificate was valid till 10th February, 2022.
20.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports on testing of drug product.

Decision: Deferred for following:

- **Submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Pharmaceutical equivalence study with complete testing of the drug product and the comparator product including the tests recommended by innovator product.**
- **Results of tests of content uniformity and loss on drying as recommended by literature of innovator product.**
- **Report of analytical method validation studies of the drug product.**
- **Scientific justification for the selection of time points for stability studies in the light of ICH/WHO relevant guidelines.**
- **Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided.**

1109.	Name, address of Applicant / Marketing Authorization Holder	M/s Relizon Pharmaceuticals, Plot No. 118, Sundar industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Relizon Pharmaceuticals, Plot No. 118, Sundar industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23866 Dated 31-08-2021
	Details of fee submitted	PKR 20,000/-: Dated 04-01-2021 PKR 10,000/- Dated 28-07-2021
	The proposed proprietary name / brand name	Dexon 60mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Dexlansoprazole DDR Pellets eq. Dexlansoprazole…….60mg
	Pharmaceutical form of applied drug	White to grayish-white colored granular pellets filled in empty capsule shell # 3 (Orange Cap and Ivory Body) Alu Alu Pack in Carton
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	3 × 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 60mg Capsule by M/s Takeda Pharms USA, (USFDA Approved).
	For generic drugs (me-too status)	Dexiva 60mg Capsule by M/s Ferozsons Laboratories, (Reg # 091334)
	GMP status of the Finished product manufacturer	New license granted on 19/03/2022 Tablet (General Tablet Capsule Dry Powder suspension) section approved.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Islamabad.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Dexlansoprazole Pellets is not present in USP/BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C±2°C/ 65% ± 5%RH for 72 months Accelerated: 40°C±2°C/ 75% ± 5%RH for 6 months Batches: (DLP123T, DLP124T, DLP125T)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Dexiva 60mg Capsule (Batch # 039C48) by M/s Ferozsons Laboratories by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same product that is Dexon 60mg capsule by M/s Relizon Pharma in Acid media (pH 0.1N HCl) & Phosphate Buffer (pH 5.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Road, Islamabad. Pakistan.		
API Lot No.	DLP-467		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST-01	ST-02	ST-03
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	19-09-2019	20-09-2019	21-09-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Applicant has submitted GMP certificate having following information on it: Certificate No. F.3-26/2019-Addl. Dir. (QA&LT-1) Issued to: M/s. Vision Pharmaceuticals Validity: 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of Delivery challan for the purchase of Dexlansoprazole DDR pellets 22.5% (quantity 2.5 kg) from M/s. Vision Pharmaceuticals, Islamabad which is a local source.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has not submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has not submitted any document.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	You have claimed USP specification in module 1 while the product monograph is not present in available monograph.	This is a typographical mistake. The product monograph is in-house.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method validation of the test method for the determination of Dexlansoprazole 22.5% DDR pellets by performing specificity, linearity, accuracy, intermediate precision, repeatability and robustness.
3.	Justify why pharmaceutical equivalence and CDP studies were not performed against innovator product (Dexilant).	We use Dexiva capsule for pharmaceutical equivalence and CDP studies since this brand is easily available in market.
4.	Justify why pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product.	Not submitted.
5.	Clarify the type of capsule shell used in dexlansoprazole pellets since innovator product has specified hypromellose capsule shells.	We use hard gelatin capsule for the filling of Dexon Capsule.
6.	If the product monograph is present in USP, justify how you have adopted specifications and analytical procedures of drug substance manufacturer.	The product is not available in USP, so we use in-house method.
7.	The tests of content uniformity and loss on drying were not included in the submitted specifications as recommended by literature of innovator product.	Not submitted
8.	Submit analytical procedures of all the tests mentioned in finished drug product specifications.	The firm has submitted analytical procedures used for testing of drug product.
9.	Justify analytical method for assay testing without performance of analytical method verification / validation studies. Justify your statement that since the product is	The firm has not submitted analytical method validation studies of drug product.

	pharmacopoeial therefore analytical process validation is not mandatory in the light of Pharmacopoeial/ICH/WHO guidelines.	
10.	The results of batch analysis and stability data reflect that tests of content uniformity and loss on drying have not been performed throughout stability studies. Justify your stability study data without performance of these tests.	Not submitted.
11.	Justify the selection of time points for stability studies in the light of relevant guidelines.	Not submitted.
12.	Submit copy of invoice for evidence of purchase of pellets used in the development of analysis of each batch of drug product.	The firm has submitted copy of invoice (600714) for the purchase of Dexlansoprazole DDR pellets 22.5% (batch # DLP467, 3kg) dated 12-09-2019.
13.	Provide copy of Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Not submitted
14.	Submit copy of GMP certificate of drug substance manufacturer.	The firm has submitted copy of GMP certificate for M/s Vision Pharmaceuticals issued by Additional Director, DRAP, Islamabad. The certificate was valid till 10th February, 2022.
15.	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports on testing of drug product.

Decision: Deferred for following:

- **Submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Pharmaceutical equivalence study with complete testing of the drug product and the comparator product including the tests recommended by innovator product.**
- **Results of tests of content uniformity and loss on drying as recommended by literature of innovator product.**
- **Report of analytical method validation studies of the drug product.**
- **Scientific justification for the selection of time points for stability studies in the light of ICH/WHO relevant guidelines.**
- **Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided.**

1110.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma (Pvt) Limited., Plot no. 29-30, Sector 27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt) Limited., Plot no. 29-30, Sector 27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34229 Dated 31-12-2021
	Details of fee submitted	Rs. 30,000/-: Dated 31-12-2021
	The proposed proprietary name / brand name	Valsop Solution for Injection and Infusion 500mg/5ml

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Valproate Sodium equivalent to Valproic acid……..…..500mg
	Pharmaceutical form of applied drug	Clear, colorless solution free from foreign particles packed in clean glass ampoule USP with a package insert in a unit carton.
	Pharmacotherapeutic Group of (API)	Antiepileptic ATC code: N03AG01
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	5ml × 1's 5ml × 5's 5ml × 10's
	Proposed unit price	Rs. 200 (5ml x 1's)/-, Rs. 800 (5ml x 5's)/-, Rs. 1,600 (5ml x 10's)/-
	The status in reference regulatory authorities	Valproate Sodium Injection 100mg/ml by M/s Fresenius Kabi USA, USFDA Approved.
	For generic drugs (me-too status)	Epival Injection 500mg/5ml by M/s Abbott Laboratories (Pakistan) Ltd. (Reg # 023349)
	GMP status of the Finished product manufacturer	Last GMP Inspection dated 03-12-2021 concludes that M/s Getz Pharma Pvt. Ltd. is considered to be operating at an acceptable level of compliance of GMP requirements. Liquid Injectable (General) section approved.
	Name and address of API manufacturer.	M/s Sun Pharmaceutical Industries Ltd., Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamilnadu – 603 303, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance has been submitted. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies	Stability study conditions: Real time: 30°C±2°C / 75% ± 5%RH for 72 months Accelerated: 40°C±2°C / 75% ± 5%RH for 6 months Batches: (PDMSDMFL314, PDMSDMFL315, PDMSDMFL316).
	Module-III (Drug Product):	The firm has submitted details of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence	Pharmaceutical equivalence has been established against Epival Injection 500mg/5ml (Batch # 212366XY) by M/s Abbott Laboratories (Pakistan) Ltd., by performing quality tests (Appearance, clarity of solution, Assay, pH and nominal volume).
	Analytical method validation/verification of product	Method verification studies have been submitted including, system suitability, specificity, linearity, accuracy, precision repeatability, stability of solution and range.

STABILITY STUDY DATA

Manufacturer of API	M/s Sun Pharmaceutical Industries Ltd., Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamilnadu – 603 303, India.		
API Lot No.	SDMNF20087		
Description of Pack (Container closure system)	Clear glass ampoule in a unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	541DS01	541DS02	541DS03
Batch Size	1400 Ampoules	1400 Ampoules	1400 Ampoules
Manufacturing Date	29-07-2020	30-07-2020	30-07-2020
Date of Initiation	21-08-2020	21-08-2020	21-08-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Estine (Ebastine) tablets 10mg & 20mg which was conducted on 06th May 2019 and was presented in 289th meeting of Registration Board held on 14th - 16th May 2019. The case was approved and the inspection report confirms following points:

<table>
<tr><td></td><td></td><td>• The HPLC software is 21CFR Compliant as per record available with the firm.
• Audit trail on the testing reports is available.
• Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
• Related manufacturing area, equipment, personnel and utilities are GMP compliant.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of Good Manufacturing Practice (GMP) certificate no. K. Dis. No. 17264/D1/4/2018 issued by Department of Food Safety and Drug Control Administration Tamil Nadu India. It is valid till 31-12-2021.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice attested by Assistant Director (I&E) DRAP, Karachi, has been submitted.
<table>
<tr><th>Batch no.</th><th>Invoice no.</th><th>Quantity imported</th><th>Date of approval</th></tr>
<tr><td>SDMNF 20087</td><td>7000047066</td><td>3.5kg</td><td>17-06-2020</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated).</td></tr>
</table>

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	Copy of GMP inspection report / GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	The firm has submitted copy of GMP certificate granted based on inspection conducted on 13-01-2022.
2.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical Method Verification studies including specificity, linearity, repeatability and range performed by the Drug Product manufacturer. This is to bring to your kind attention that we have used 100% API without any placebo in Analytical Method Verification Studies of Sodium Valporate; therefore, requirement of accuracy is not applicable. Further, we have performed linearity to check area response of the sample as the concentration of the sample raised within working range of sample i.e., 50% - 150%.
3.	Justify the acceptance criteria for nominal volume in finished product specifications as "Not less than 5ml". Moreover, justification	This is to inform your good office that we have developed the product formulation of Valsop Solution for Injection and Infusion 500mg/5ml by Benchmarking the product **Epival 500mg /**

	is required for inclusion in the finished product specification.	**5ml Injection**. Since the reference product has pack size of 5ml for injection, therefore we have adopted the same volume for our product per ampoule. Further, acceptance criteria for nominal volume in finished product specifications as "Not less than 5ml" is derived from USP chapter **⟨697⟩ Container Content For Injections** wherein it is mentioned that *"The volume is NLT the nominal volume in the case of containers examined individually".*

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will perform accuracy studies as part of verification studies of analytical method of drug substance before issuance of Registration Letter.**

1111.	Name, address of Applicant / Marketing Authorization Holder	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32573 Dated 30-11-2021
	Details of fee submitted	PKR 30,000/-: Dated 04-11-2021
	The proposed proprietary name / brand name	Silo Capsules 8mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Silodosin…….…8mg
	Pharmaceutical form of applied drug	White to off white color granular powder filled in blue and gray hard gelatin shells.
	Pharmacotherapeutic Group of (API)	Alpha adrenoreceptor antagonist ATC code: G04CA04
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	10's' 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rapaflo capsules 8mg by M/s Watson Laboratories, Inc. Corona, CA 92880 USA (USFDA approved)
	For generic drugs (me-too status)	Sildoso Capsule 8 mg of M/s CCL Pharmaceuticals (Reg No: 106273)
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 09-11-2020. Capsules section provided.

	Name and address of API manufacturer.	Name: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: Jiangkou Development Zone, Huangyan, Taizhou City, Zhejiang province, China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Silodosin is not present in any Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Long term: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (T-01, T-02, T-03)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Sildoso capsules 8mg (Batch # SA2) by CCL Pharmaceuticals by performing quality tests (Identification, Disintegration time, Dissolution, Assay). CDP has been performed against the same comparator product. Dissolution profiles of both products (sildoso capsules 8mg and silo capsules 8mg) were compared at three pH (1.2, 4.5, and 6.8) graphically and statistically.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, Robustness, accuracy, precision (Repeatability), specificity.
STABILITY STUDY DATA		
Manufacturer of API		Name: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Factory Address: No.15, Donghai 5th Avenue, Zheijiang provincial chemical and medical raw materials base Linhai Zone, Taizhou City, Zhejiang province, China. Office address: Jiangkou Development Zone, Huangyan, Taizhou City, Zhejiang province, China.

API Lot No.	13000-180801		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Long term: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Long term: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Long term: 0, 3, 6 (Months)		
Batch No.	Trial#01	Trial#02	Trial#03
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	16-01-2020	16-01-2020	16-01-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	Mekolade Tablets containing Metolazone 5mg DRAP Registration no. 108059
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 202004051 issued by Zhejiang Medical Product Service Center for information publicity and Development Issue & Valid Upto Dt: 23-12-2020 – 22-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Letter to Assistant Director (Reg III) (R&I dated; 13-07-2018) is submitted wherein the permission to import different APIs including Silodosin for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of evaluator:

Sr. No.	Observations	Response by the firm
1.	Provide copies of the drug substance specifications and analytical procedures used for routine testing of the drug substance by both Drug Substance and Drug Product manufacturer.	Copies of the drug substance specifications and analytical procedures used for routine testing of the drug substance by both Drug Substance and Drug Product manufacturer have been submitted.
2.	Analytical method verification studies including specificity, accuracy and repeatability performed by the Drug Product Manufacturer for both compendial as well as non-compendial drug substances shall be submitted.	Analytical method verification studies including specificity, accuracy, and repeatability, were performed and are now submitted as per the requirement.

3.	The drug substance exists in three polymorphic forms. The polymorphic form of drug substance used has not been specified.	The drug substance exists in β polymorphic form as clearly mention in DMF.
4.	Justify why pharmaceutical equivalence and CDP studies were not performed with the innovator product (RAPAFLO).	Innovator product was not available in Pakistan. As a result, we selected the DRAP-approved reference product that was currently available in the market.
5.	Justify why assay limits of Silodosin Capsules 8mg are different in specifications (90-110%), batch analysis (90-105%) and pharmaceutical equivalence (90-105%).	The assay limit of Silodosin Capsules 8mg is 90-110% which is clearly mentioned in the submitted method of analysis and stability data sheet. There was a typographic error where the assay limit of 90-105% was written in batch analysis and pharmaceutical equivalence instead of 90-110%.
6.	The drug substance silodosin is light sensitive and cautions should be taken to avoid exposure to light during the complete analysis of the drug substance and drug product, justify your performance without taking into consideration the photosensitive nature of the drug substance.	The silodosin drug substance is stored in well closed container protected from light and the product is processed under diffused light. For analysis of the drug substance and product amber color flask are used to protect from direct exposure of light.

Decision: Approved.

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

1112.		
	Name, address of Applicant / Marketing Authorization Holder	M/s Pacific Pharmaceuticals Limited, 30 Km, Multan Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited, 30 Km, Multan Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26941 Dated 29-09-2021
	Details of fee submitted	PKR 20,000/-: Dated 25-12-2020
	The proposed proprietary name / brand name	Ritufen 125mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Terbinafine as hydrochloride……125mg
	Pharmaceutical form of applied drug	White or almost white round, biconvex tablets with a breakline on one side.
	Pharmacotherapeutic Group of (API)	Allylamine antifungal ATC code: D01BA02
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1 × 10's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	LAMISIL® (terbinafine hydrochloride) 125 mg and 250 mg Tablet, TGA approved.
	For generic drugs (me-too status)	Terbin 125mg Tablet of M/s Martin Dow (Reg# 028975)
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 07-03-2019.
	Name and address of API manufacturer.	M/s Zhejiang East-Asia pharmaceutical Co., Ltd. Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, control of drug substance, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C±2°C/65% ± 5%RH for 24 months Accelerated:40°C±2°C/75% ± 5%RH for 6 months Batches: DC-013-1707001, DC-013-1707002, DC-013-1707003
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Lamisil 125mg Tablet (Batch no. WW402(8)) of Novartis by performing description, average weight, disintegration time, dissolution and assay. CDP has been performed against the same product in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Zhejiang East-Asia pharmaceutical Co., Ltd.	

	Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China.		
API Lot No.	DC-013-2006007		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time:24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTB0109O	TTB0209O	TTB0309O
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	08-09-2019	08-09-2019	08-09-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (No: ZJ20180010) of M/s Zheijiang East-Asia Pharmaceutical co., Ltd, China issued by China Food and Drug Administration. It is valid till 23-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Terbinafine hydrochloride (60 kg, DC-013-2006007) attested by Assistant Director (I & E), Lahore dated 26-06-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has not submitted audit trail on testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted	The firm has submitted method verification studies of test method of drug substance using system suitability, specificity, accuracy, precision and linearity.
2.	Justify why you have mentioned Sodium starch glycolate two times in master formulation.	In master formulation, we have mentioned sodium starch glycolate two time because it is used as disintegrant by function and divided into two portions, one portion used at pre-mixing stage and other portion used at final mixing stage.

3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (No: ZJ20180010) of M/s Zheijiang East-Asia Pharmaceutical co., Ltd, China issued by China Food and Drug Administration. It is valid till 23-01-2023.
4.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Terbinafine hydrochloride (60 kg, DC-013-2006007) attested by Assistant Director (I & E), Lahore dated 26-06-2020.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted.
7.	Justify the selection of storage conditions of 30°C/35% RH for ongoing stability studies of drug product.	It was typographic error. We have performed stability study according to ICH guidelines. Stability study conditions are mentioned as below: Real time: 30 °C ± 2 °C/ 65% ± 5% RH Accelerated: 40 °C ± 2 °C/ 75% ± 5% RH

Decision: Approved.

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

1113.	Name, address of Applicant / Marketing Authorization Holder	M/s Hansel Pharmaceuticals Private Limited, Plot No. 02, Pharma City, 30-km Multan Road, Lahore-Pakistan.
	Name, address of Manufacturing site.	M/s Hansel Pharmaceuticals Private Limited, Plot No. 02, Pharma City, 30-km Multan Road, Lahore-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24079 Dated 01-09-2021
	Details of fee submitted	PKR 20,000/- Dated 28-08-2020 PKR 10,000/- (Bank slip #6614935760)
	The proposed proprietary name / brand name	Femipla-Ject Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1mL ampoule contains: Norethisterone Enanthate……..50mg Estradiol Valerate……..5mg
	Pharmaceutical form of applied drug	Oily solution for Injection (IM)
	Pharmacotherapeutic Group of (API)	Progestogens (Contraceptive) ATC Code: G03AC
	Reference to Finished product specifications	Hansel Specifications
	Proposed Pack size	1ml × 1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Estradiol valerate/Norethisterone enantate Solution for injection 5mg/50mg/mL (WHO prequalified product).
	For generic drugs (me-too status)	FEMI-JECT Injection by M/s Bayer pharma (Pvt.) Ltd. Lahore, (Reg # 022372).
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 15-05-2019. The firm has provided Liquid Injectable Hormone section.
	Name and address of API manufacturer.	**Norethisterone Enanthate:** M/s Zhejiang Xianju Junye Pharmaceutical Co., Ltd., No.1 Lingxiu Road, Modern Industrial Centralization zone, Xianju, Taizhou, Zhejiang, China. **Estradiol Valerate:** M/s ASG. Biochem Pvt. Ltd., Ganganagar, 24 Parganas, West Bengal India.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubility, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances (Norethisterone Enanthate+ Estradiol Valerate).
	Stability studies	**Norethisterone Enanthate:** Stability study conditions: Real time: 30°C±2°C/65% ± 5%RH for 24 months. Accelerated: 40°C±2°C/75%±5%RH for 6 months. Batches: (30761308001, 30761308002, 30761308003). **Estradiol Valerate**: Stability study conditions: Real time: 30°C±2°C/65% ± 5%RH for 48 months. Accelerated: 40°C±2°C/75%±5%RH for 6 months. Batches: (ESVZ01A002, ESVZ01A005, ESVZ01A006).
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Femi-Ject by Bayer Pharma by performing quality tests (Identification, Assay, pH, Particulate matter, Sterility). Dissolution profile in not applicable in Femipla-Ject Injection.	
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API	**Norethisterone Enanthate:** M/s Zhejiang Xianju Junye Pharmaceutical Co., Ltd., No.1 Lingxiu Road, Modern Industrial Centralization zone, Xianju, Taizhou, Zhejiang, China. **Estradiol Valerate:** M/s ASG. Biochem Pvt. Ltd., Ganganagar, 24 Parganas, West Bengal India.		
API Lot No.	Norethisterone Enanthate: 3076190701M Estradiol Valeartae: ESVZ01A016		
Description of Pack (Container closure system)	1 amber color ampoule of 1mL packed in unit carton along with disposable syringe, alcohol swab and a leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FT-001	FT-002	FT-003
Batch Size	2000 Ampoules	2000 Ampoules	2000 Ampoules
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	08-10-2019	10-10-2019	12-10-2019
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	It is the submission of first dossier on CTD format, thus no inspection conducted regarding stability studies of the applied product.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Norethisterone Enanthate:** The firm has submitted copy of GMP certificate for M/s Zhejiang Xianju Junye Pharmaceutical Co. issued by national medical products administration valid till 29-11-2024. **Estradiol valerate:** The firm has submitted copy of GMP certificate for M/s ASG Biochem Pvt. Ltd. issued by Director of Drugs Control, Govt. of West Bangal. The license is valid till 24-10-2024.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Norethisterone Enanthate**: The firm has submitted copy of invoice specifying import of Norethisterone enanthate 20gm (Batch # 3076190701M) attested by Assistant Director (I & E) Lahore dated 30-09-2019. **Estradiol Valerate:** The firm has submitted copy of invoice specifying import of estradiol valerate 20gm (Batch # 190401) attested by Assistant Director (I & E) Lahore dated 01-08-2019.	

4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable.
6.	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	Provide copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.	The firm has provided copies of drug substance specifications and analytical procedures.
2.	Provide certificate of Analysis (CoA) of the drug substance (Estradiol valerate) from drug substance manufacturer.	The firm has submitted certificate of analysis of Estradiol valerate from drug substance manufacturer.
3.	Provide the details of the reference product including batch number, manufacturing date and expiry date.	The firm has submitted details of reference product: Name: FEMI-JECT Injection Batch number: MP06249 Mfg date: 09-2019 Expiry date: 09-2024
4.	Justify why you have not performed the tests of clarity of solution and bacterial endotoxin in the pharmaceutical equivalence study.	Not submitted
5.	Justify why tests of pH and ampoule sealing are included in specifications under analytical procedures (3.2.P.5.2). Moreover, provide the pharmacopoeial reference where the test of "ampoule sealing" is mentioned	Not submitted
6.	Justify the test of pH throughout stability studies for development batches of oily injection.	Not submitted
7.	Reference of previous approval of applications with stability study data of the firm (if any).	The firm has submitted previous approvals of products in this section.
8.	Submit compliance Record of HPLC software 21CFR. The submitted audit trail reports do not specify the software used in HPLC and further clarify the demo version of software.	The firm has not submitted audit trail record of HPLC software 21 CFR.

Decision: Deferred for following:

- **Evidence of required manufacturing facility / section from Licensing Division.**
- **Scientific justification for not performing the tests of clarity of solution and bacterial endotoxin in the pharmaceutical equivalence study.**
- **Scientific justification for the test and limits of pH and ampoule sealing test for oily injection.**
- **Scientific justification for performing the test of pH throughout stability studies for development batches of oily injection.**

Agenda of Evaluator PEC-VII

Case no. 01 Registration applications for local manufacturing of (Human) drugs

Case no. 02 Registration applications of drugs for which stability study data is submitted Registration applications for Form 5D

a) Form 5D cases Exemption

114.	**Name and address of manufacturer / Applicant**	**M/s Neutro pharma (Pvt) Limited 9.5 km Sheikhupura road Lahore**
	Brand Name +Dosage Form + Strength	Neuleval 0.63 mg Respules
	Composition	Each vial contains: Levalbuterol as HCl…….0.63 mg
	Diary No. Date of R& I & fee	Dy. No. 6825, 22/02/2018, Rs: 50,000/- Dated: 21/02/2018 (#0730322)
	Pharmacological Group	Relatively selective beta 2- Adrenergic receptor agonist
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	Xopenex inhalation solution 0.63mg, 0.021% (3ml) of M/s Oak Pharms Inc. (USFDA Approved)
	Me-too status	Livabel respules 0.63mg by Hudson Pharma
	GMP status	The last inspection conducted on 18-07-2017 concluding that the firm maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Neuleval 0.63 mg Respules		
Name of Manufacturer	M/s Neutro pharma (Pvt) Limited 9.5 km Sheikhupura road Lahore		
Manufacturer of API	M/S Aarti industries Ltd, India.		
API Lot No.	**Levalbuterol:** LH-18003		
Description of Pack (Container closure system)	As per SRO (3ml)		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C/NMT 25% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (month) Real Time: 0,3,6 (month)		
Batch No.	LEV-NUB-0.63-001-19	LEV-NUB-0.63-002-19	LEV-NUB-0.63-003-19
Batch Size	3L	3L	3L
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	11-12-2019	12-12-2019	11-12-2019
No. of Batches	03		
Date of Submission	23-07-2020 (18067)		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

Sr. No.	Documents to Be Provided	Status
9.	Reference of previous approval of applications with stability study data of the firm	
10.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Levalbuterol**: Copy of COA (Batch# LH-18003) from M/S Aarti industries Ltd unit-IV, plot No E-50 midc tarapur taluka and district palghar Maharashtra state India is submitted.
11.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes
12.	Stability study data of API from API manufacturer	Yes
13.	Approval GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate of cGMP: KD/65674/2018/11/22940 Dated: 21-3-2018 from office of the commissioner food and drug administration MS Bandra, Kurla complex, Mumbai
14.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice for API from India, which is AD (Lahore) attested and invoice for batch 801805254 (AD attested) provided
15.	Protocols followed for conduction of stability study	Provided
16.	Method used for analysis of FPP	Provided
17.	Drug-excipients compatibility studies (where applicable)	Not applicable
18.	Complete batch manufacturing record of three stability batches.	Provided
19.	Record of comparative dissolution data (where applicable)	Not applicable
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
21.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes
22.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

REMARKS OF EVALUATOR

S No	Deficiency	Response
1.	In RRA, XOPENEX Inhalation Solution Concentrate is supplied in 0.5 mL unit-dose vials that must be diluted with normal saline before administration by nebulization. Each 0.5 mL unit-dose vial contains 1.25 mg of levalbuterol (as 1.44 mg of levalbuterol HCl), sodium chloride to adjust tonicity, and hydrochloric acid to adjust the pH but in applied formulation sulfuric acid is used instead of HCl	In Xopenex inhalation solution sulfuric acid instead of hydrochloric acid is used to adjust the pH. Literature is provided
2.	In RRA active is as levalbuterol as HCl but in form 5, firm applied as just levalbuterol HCl	Firm has mistakenly written levalbuterol HCL on form 5 while according to USP specs. It is

		Levalbuterol as HCl so form 5 is revised
3.	Availability of section	Section of small and large volume parenteral (blow filled and sealing in LDPE) available
4.	The USP product release specifications tests for this including tests for content uniformity, enantiomeric purity and impurity testing Justify the exemption of these tests.	Content uniformity test and impurities are provided
5.	The storage condition on accelerated data is mentioned as 40°C ± 2°C / 25% as aqueous solution is packed in LDPE ampoule according to ICH guideline Aqueous-based products packaged in semi-permeable containers should be evaluated for potential water loss in addition to physical, chemical, biological, and microbiological stability	The applied formulation is filled in LDPE container that is why storage condition on accelerated stability data is mentioned as at Real time: 30°C ± 2°C / 35% ± 5%RH and Accelerated: 40°C ± 2°C / 25% ± 5%RH
6.	The valid GMP certificate of M/S Aarti industries Ltd, India is not provided. Provided one was valid till 16 March	GMP certificate of M/S Aarti industries Ltd, India valid till 09-Jun 2023 is provided
7.	Documents for the procurement of API with approval from DRAP is needed with AD attestation	Provided
8.	API stability at Accelerated and real time conditions is not submitted	Provided
9.	Protocols of conducting stability studies for the specific product is needed.	Protocols of conducting stability studies for the specific product is needed.
10.	At some places like form 5D container is mentioned as vial and some were as LDPE ampule. Clarification is needed	The firm has mistakenly written vial on form 5 D while in actual the product is packed in LDPE ampoule
11.	The DML of neutro is expired valid till 5 year from 10-05-2015	The inspection for drug manufacturer license renewal is already conducted and waiting for license renewal
12.	The internal method used for analysis of FPP by the manufacture in details containing all dilutions preparations and calculations is needed	Product Test Method and Specifications for Neuleval Respules available
13.	Reference of previous approval of applications with stability study data of the firm	Reference of previous approval of application of dexol 30 mg capsule and 60 mg capsule approved in board meeting with stability study data of the firm is provided. No inspection of this dosage form is conducted
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
15.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

1115.	**Name and address of manufacturer / Applicant**	**M/s Neutro pharma (Pvt) Limited 9.5 km Sheikhupura road Lahore**
	Brand Name +Dosage Form + Strength	Neuleval 0.31 mg Respules
	Composition	Each vial contains: Levalbuterol as HCl…….0.31 mg
	Diary No. Date of R& I & fee	Dy. No. 6876, 22/02/2018, Rs: 50,000/- Dated: 19/02/2018 (#0730321)

	Pharmacological Group	Relatively selective beta2- Adrenergic receptor agonist
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	Xopenex inhalation solution 0.31 mg (3ml) of M/s Oak Pharms Inc. (USFDA Approved)
	Me-too status	NA
	GMP status	The last inspection conducted on 18-07-2017 concluding that the firm maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Neuleval 0.31 mg Respules		
Name of Manufacturer	M/s Neutro pharma (Pvt) Limited 9.5 km Sheikhupura road Lahore		
Manufacturer of API	M/S Aarti industries Ltd, India.		
API Lot No.	**Levalbuterol:** : LH-18003		
Description of Pack (Container closure system)	As per SRO (3ml)		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C/NMT 25% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (month) Real Time: 0,3,6 (month)		
Batch No.	LEV-NUB-0.31-001-19	LEV-NUB-0.31-002-19	LEV-NUB-0.31-003-19
Batch Size	210 ampoules	210 ampoules	210 ampoules
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	12-12-2019	12-12-2019	12-12-2019
No. of Batches	03		
Date of Submission	23-07-2020 (18066)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
23.	Reference of previous approval of applications with stability study data of the firm	
24.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Levalbuterol**: Copy of COA (Batch# LH-18003) from M/S Aarti industries Ltd unit-IV, plot No E-50 midc tarapur taluka and district palghar Maharashtra state India is submitted.
25.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes
26.	Stability study data of API from API manufacturer	Yes

27.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate of cGMP: KD/65674/2018/11/22940 Dated: 21-3-2018 from office of the commissioner food and drug administration MS Bandra, Kurla complex, Mumbai
28.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice for API from India, which is AD (Lahore) attested and invoice for batch 801805254 (AD attested) provided
29.	Protocols followed for conduction of stability study	Provided
30.	Method used for analysis of FPP	Provided
31.	Drug-excipients compatibility studies (where applicable)	Not applicable
32.	Complete batch manufacturing record of three stability batches.	Provided
33.	Record of comparative dissolution data (where applicable)	Not applicable
34.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
35.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes
36.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

REMARKS OF EVALUATOR

S No	Deficiency	Response
1.	In RRA, XOPENEX Inhalation Solution Concentrate is supplied in 0.5 mL unit-dose vials that must be diluted with normal saline before administration by nebulization. Each 0.5 mL unit-dose vial contains 1.25 mg of levalbuterol (as 1.44 mg of levalbuterol HCl), sodium chloride to adjust tonicity, and hydrochloric acid to adjust the pH but in applied formulation sulfuric acid is used instead of HCl	In Xopenex inhalation solution sulfuric acid instead of hydrochloric acid is used to adjust the pH. Literature is provided
2.	In RRA active is as levalbuterol as HCl but in form 5, firm applied as just levalbuterol HCl	Firm has mistakenly written levalbuterol HCL on form 5 while according to USP specs. It is Levalbuterol as HCl so form 5 is revised
3.	Availability of section	Section of small and large volume parenteral (blow filled and sealing in LDPE) available
4.	The USP product release specifications tests for this including tests for content uniformity, enantiomeric purity and impurity testing Justify the exemption of these tests.	Content uniformity test and impurities are provided
5.	The storage condition on accelerated data is mentioned as 40°C ± 2°C / 25% as aqueous solution is packed in LDPE ampoule according to ICH guideline Aqueous-based products packaged in semi-permeable containers should be evaluated for potential	The applied formulation is filled in LDPE container that is why storage condition on accelerated stability data is mentioned as at Real time: 30°C ± 2°C / 35% ± 5%RH and Accelerated: 40°C ± 2°C / 25% ± 5%RH

	water loss in addition to physical, chemical, biological, and microbiological stability	
6.	The valid GMP certificate of M/S Aarti industries Ltd, India is not provided. Provided one was valid till 16 March	GMP certificate of M/S Aarti industries Ltd, India valid till 09-Jun 2023 is provided
7.	Documents for the procurement of API with approval from DRAP is needed with AD attestation	Provided
8.	API stability at Accelerated and real time conditions is not submitted	Provided
9.	Protocols of conducting stability studies for the specific product is needed.	Protocols of conducting stability studies for the specific product is needed.
10.	At some places like form 5D container is mentioned as vial and some were as LDPE ampule. Clarification is needed	The firm has mistakenly written vial on form 5 D while in actual the product is packed in LDPE ampoule
11.	The DML of neutro is expired valid till 5 year from 10-05-2015	The inspection for drug manufacturer license renewal is already conducted and waiting for license renewal
12.	The internal method used for analysis of FPP by the manufacture in details containing all dilutions preparations and calculations is needed	Product Test Method and Specifications for Neuleval Respules available
13.	Reference of previous approval of applications with stability study data of the firm	Reference of previous approval of application of dexol 30 mg capsule and 60 mg capsule approved in board meeting with stability study data of the firm is provided. No inspection of this dosage form is conducted
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
15.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks:

- The DML of neutro is expired valid till 5 year from 10-05-2015
- The internal Method used for analysis of FPP by the manufacture in details containing all dilutions and calculations is needed
- Reference of previous approval of applications with stability study data of the firm
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

1116.	**Name and address of manufacturer / Applicant**	**M/s Neutro pharma (Pvt) Limited 9.5 km Sheikhupura road Lahore**
	Brand Name +Dosage Form + Strength	Neuleval 1.25 mg Respules
	Composition	Each vial contains: Levalbuterol as HCl…….1.25 mg
	Diary No. Date of R& I & fee	Dy. No. 6877, 22/02/2018, Rs: 50,000/- Dated: 19/02/2018 (#0723500)
	Pharmacological Group	Relatively selective beta2- Adrenergic receptor agonist
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulator Authorities	Xopenex inhalation solution 1.25 mg (3ml) of M/s Oak Pharms Inc. (USFDA Approved)
	Me-too status	NA
	GMP status	The last inspection conducted on 18-07-2017 concluding that the firm maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Neuleval 1.25 mg Respules		
Name of Manufacturer	M/s Neutro pharma (Pvt) Limited 9.5 km Sheikhupura road Lahore		
Manufacturer of API	M/S Aarti industries Ltd, India.		
API Lot No.	**Levalbuterol:** LH-18003		
Description of Pack (Container closure system)	As per SRO / (3ml)		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C/NMT 25% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (month) Real Time: 0,3,6 (month)		
Batch No.	LEV-NUB-1.25-001-19	LEV-NUB-1.25-002-19	LEV-NUB-1.25-003-19
Batch Size	3L	3L	3L
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	13-12-2019	13-12-2019	13-12-2019
No. of Batches	03		
Date of Submission	23-07-2020 (18068)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Levalbuterol**: Copy of COA (Batch# LH-18003) from M/S Aarti industries Ltd unit-IV, plot No E-50 midc tarapur taluka and district palghar Maharashtra state India is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Yes
4.	Stability study data of API from API manufacturer	Yes
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate of cGMP: KD/65674/2018/11/22940 Dated: 21-3-2018 from office of the commissioner food and drug administration MS Bandra, Kurla complex, Mumbai
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice for API from India, which is AD (Lahore) attested and invoice for batch 801805254 (AD attested) provided

7.	Protocols followed for conduction of stability study	Provided
8.	Method used for analysis of FPP	Provided
9.	Drug-excipients compatibility studies (where applicable)	Not applicable
10.	Complete batch manufacturing record of three stability batches.	Provided
11.	Record of comparative dissolution data (where applicable)	Not applicable
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

REMARKS OF EVALUATOR

S No	Deficiency	Response
1.	In RRA, XOPENEX Inhalation Solution Concentrate is supplied in 0.5 mL unit-dose vials that must be diluted with normal saline before administration by nebulization. Each 0.5 mL unit-dose vial contains 1.25 mg of levalbuterol (as 1.44 mg of levalbuterol HCl), sodium chloride to adjust tonicity, and hydrochloric acid to adjust the pH but in applied formulation sulfuric acid is used instead of HCl	In Xopenex inhalation solution sulfuric acid instead of hydrochloric acid is used to adjust the pH. Literature is provided
2.	In RRA active is as levalbuterol as HCl but in form 5, firm applied as just levalbuterol HCl	Firm has mistakenly written levalbuterol HCL on form 5 while according to USP specs. It is Levalbuterol as HCl so form 5 is revised
3.	Availability of section	Section of small and large volume parenteral (blow filled and sealing in LDPE) available
4.	The USP product release specifications tests for this including tests for content uniformity, enantiomeric purity and impurity testing Justify the exemption of these tests.	Content uniformity test and impurities are provided
5.	The storage condition on accelerated data is mentioned as 40°C ± 2°C / 25% as aqueous solution is packed in LDPE ampoule according to ICH guideline Aqueous-based products packaged in semi-permeable containers should be evaluated for potential water loss in addition to physical, chemical, biological, and microbiological stability	The applied formulation is filled in LDPE container that is why storage condition on accelerated stability data is mentioned as at Real time: 30°C ± 2°C / 35% ± 5%RH and Accelerated: 40°C ± 2°C / 25% ± 5%RH
6.	The valid GMP certificate of M/S Aarti industries Ltd, India is not provided. Provided one was valid till 16 March	GMP certificate of M/S Aarti industries Ltd, India valid till 09-Jun 2023 is provided

7.	Documents for the procurement of API with approval from DRAP is needed with AD attestation	Provided
8.	API stability at Accelerated and real time conditions is not submitted	Provided
9.	Protocols of conducting stability studies for the specific product is needed.	Protocols of conducting stability studies for the specific product is needed.
10.	At some places like form 5D container is mentioned as vial and some were as LDPE ampule. Clarification is needed	The firm has mistakenly written vial on form 5 D while in actual the product is packed in LDPE ampoule
11.	The DML of neutro is expired valid till 5 year from 10-05-2015	The inspection for drug manufacturer license renewal is already conducted and waiting for license renewal
12.	The internal method used for analysis of FPP by the manufacture in details containing all dilutions preparations and calculations is needed	Product Test Method and Specifications for Neuleval Respules available
13.	Reference of previous approval of applications with stability study data of the firm	Reference of previous approval of application of dexol 30 mg capsule and 60 mg capsule approved in board meeting with stability study data of the firm is provided. No inspection of this dosage form is conducted
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
15.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

1. Section of small and large volume parenteral (blow filled and sealing in LDPE) available

Decision: Registration Board approved the applications of Neuleval 0.63 mg Respules, Neuleval 0.31 mg Respules & Neuleval 1.25 mg Respules.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of pharmaceutical equivalence studies of each strength, performed against the innovator's/comparator drug product**

Case No. 02 Registration applications of drugs for which stability study data is submitted Registration applications for Form 5F

c) Form 5F (Human)

1117.	Name, address of Applicant / Marketing Authorization Holder	**M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No26122 dated 21/09/2021
	Details of fee submitted	PKR 30,000/ dated 14/09/2021
	The proposed proprietary name / brand name	**ONDIS 8mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron Hydrochloride USP equivalent to Ondansetron ……..…8mg USP Specifications
	Pharmaceutical form of applied drug	Yellow colour, oblong shaped film coated tablet, plain from both sides
	Pharmacotherapeutic Group of (API)	Antiemetic Serotonin (5HT3) antagonists ATC Code: A04AA01
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	10's, 12's & 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Tablets 8mg, M/s. Novartis Pharmaceuticals UK Limited
	For generic drugs (me-too status)	ZOFRAN 8mg Tablet Registration # 020668 by M/s. Novartis Pharma (Pakistan) Limited
	GMP status of the Finished product manufacturer	GMP certificate issued dated: 11-08-2020
	Name and address of API manufacturer.	Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar – 393002, Dist.Bharuch, Gujarat State, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, characterization, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 36 Months Batches: (17OS001, 17OS002) Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (15OS003, 15OS004, 15OS005)

		Declaration regarding stability study data is provided in dossier
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, individual impurity and total impurity, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is ZOFRAN 8mg Tablet by M/s. Novartis Pharma Limited by performing quality tests (Appearance, Disintegration test, Average weight, Dissolution, Assay, Impurity profile, Microbial limit test). Comparative dissolution profile has been performed against the same brand that is ZOFRAN 8mg Tablet by M/s. Novartis Pharma Limited in Acidic media (pH 1.0-4.2) & Phosphate buffer (pH 6.8). The values of f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including Linearity, Accuracy, Precision including Repeatability and Specificity.

STABILITY STUDY DATA

Manufacturer of API	Cadila Pharmaceuticals Limited, India		
API Lot No.	20OS001		
Description of Pack (Container closure system)	Alu - Alu		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1,2,3,4 & 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	05-2021	05-2021	05-2021
No. of Batches	03		

Administrative Portion

19.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "EMPOLI (Empagliflozin) 10mg & 25mg Tablets" which was presented in 290th meeting of Registration Board wherein the Board decided to approve registration of this product. Date of inspection: 13th June, 2019 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available. • Adequate monitoring and control are available for stability chamber

20.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 18101065 issued by FOOD AND DRUGS CONTROL ADMINISTRATION Gujarat State valid till 18/10/2021 (Updated GMP Provided)
21.	Documents for the procurement of API with approval from DRAP (in case of import).	Detail of loan material (200gm of Ondansetron HCl) from M/s Indus Pharma (Pvt.) Ltd. of the lot supplied by M/s. Cadila Pharmaceuticals Pvt Limited under their invoice no. 3202040403 dated 10-07-2020 attested by AD (I&E), Karachi dated 19-07-2020. (Justification regarding procuring material on loan is attached here with)
22.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
23.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
24.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S #	Query	Reply
1.	Summary of the stability results observed for the accelerated and long-term studies: The long-term stability results for 3 batches instead of 2 shall be provided	Awaited The long-term stability results for 2 batches instead of 3 was provided Firm claim that " we have stability data of ondansetron HCl two batches at 30ºC we will keep third batches on 30ºC
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Detail of loan material (200gm of Ondansetron HCl) from M/s Indus Pharma (Pvt.) Ltd. of the lot supplied by M/s. Cadila Pharmaceuticals Pvt Limited under their invoice no. 3202040403 dated 10-07-2020 attested by AD (I&E), Karachi dated 19-07-2020. (Justification regarding procuring material on loan is attached here with)
3.	In RRA the drug substance used is ondansetron (as hydrochloride dihydrate) but in your proposed formulation the active is ondansetron hydrochloride	Ondansetron Tablet is available in USP and we followed the same specifications for our product. In USP, the definition of Ondansetron Tablet is as follows, "Ondansetron Tablets contain Ondansetron Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of ondansetron (C18H19N3O)"In the above statement of USP, it is clearly mentioned that the drug substance required for the preparation of Ondansetron Tablet is "Ondansetron Hydrochloride" and we followed the same drug substance for manufacturing of our product. Furthermore, the drug substance Ondansetron Hydrochloride actually exists in Dihydrate form and our drug substance is also USP claim and USP mentioned it as "Ondansetron

		Hydrochloride" in its monograph with a molecular formula of C18H19N3O · HCl · 2H2O. As water is a variable factor, therefore calculation was done on Ondansetron Hydrochloride (as is basis) and water was removed through potency adjustment. In the light of above references, it is clear that Ondansetron Hydrochloride and Ondansetron Hydrochloride Dihydrate both are same and as our specs is USP (for both drug substance and drug product), therefore we used the term Ondansetron Hydrochloride as mentioned in USP.USP monographs for both Ondansetron Hydrochloride (drug substance) and Ondansetron Hydrochloride Tablet (drug product) are attached for your kind perusal.
4.	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient Drug Product manufacturer is required.	Analytical procedure of drug substance provided
5.	Provide details comparator product against which Pharmaceutical Equivalence was established.	Pharmaceutical Equivalence have been established against the brand leader that is ZOFRAN 8mg Tablet by M/s. Novartis Pharma Limited Batch # 844519L /mfg 12-2019 by performing quality tests (Appearance, Disintegration test, Average weight, Dissolution, Assay, Impurity profile, Microbial limit test). Comparative dissolution profile has been performed against the same brand that is ZOFRAN 8mg Tablet by M/s. Novartis Pharma Limited in Acidic media (pH 1.0-4.2) & Phosphate buffer (pH 6.8). The values of f1 and f2 are in the acceptable range.
6.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Provided

Decision: Approved.

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

1118.	Name, address of Applicant / Marketing Authorization Holder	M/s Woodward Pakistan (Pvt.) Ltd. F-275, S.I.T.E, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Woodward Pakistan (Pvt.) Ltd. F-275, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17248 dated 21/06/2021
	Details of fee submitted	PKR 30,000/-: dated 07/06/2021
	The proposed proprietary name / brand name	Tilva 25 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Levosulpiride…. 25 mg
	Pharmaceutical form of applied drug	White round shaped biconvex core tablet having bisect line on one side while other side is plain
	Pharmacotherapeutic Group of (API)	Selective antagonist of dopamine D_2 receptor
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	2×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levidomed tablet by M/s Medochemie Ltd Approved in Itlay.
	For generic drugs (me-too status)	Sulvorid tablet 25 mg by M/s High Q Pharma,
	GMP status of the Finished product manufacturer	License granted on 12/02/2016 Tablet (General & Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Atlas life sciences pvt Ltd C-1/360-361, G.I.D.C, estate, Odhav, Ahmedabad India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levosulpiride is not present in pharmacopoeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 12 months Batches: (LSP-0010415, LSP-0020515, LSP-0030515)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer

		medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Sulvorid 25mg tablet by High Q Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Sulvorid 25 mg tablet by High Q pharma in Acidic media (pH 0.1 N HCl), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Atlas life sciences pvt Ltd C-1/360-361, G.I.D.C, estate, Odhav Ahmedabad-382 415, Gujrat, India.		
API Lot No.	LSP-1910020		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	PD-183	PD-184	PD-185
Batch Size	400 tablets	400 tablets	400 tablets
Manufacturing Date	05-09-2020	05-09-2020	07-09-2020
Date of Initiation	07-09-2020	10-09-2020	10-09-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. S-GMP/20021839 issued by Food and Drug control administration valid till 10/02/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Attached
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S No	Section #.	Deficiencies	Reply
1.	1.6.5	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	2.3.S.3.1	In Elucidation of Structure and other Characteristics, Discussion on the potential for isomerism and identification of stereochemistry is missing as in innovator the S isomer is active	Provided
3.	***3.2.P***	In USP dissolution method database the last recommended sampling time is 45 minutes but firm last time point is 30 minutes' justification is needed	Firm clarify that we established and validate our inhouse method for the said product which is an immediate release tablet and hence we observed that the maxiumum amount of API was dissolved in 30 minutes during comparative dissolution profile. Both our formulation and comparative brand achieve about 105%dissolution in 30 min with 100 rpm
4.	***3.2.P.4***	Firm claimed that excipients were selected for the development of product as used by innovator product, but excipients are different. Clarify	This is typographical error our firm used own excipient in our product development we use innovators products for only checking parameters or in comparative study of dissolution
5.	***3.2.P.8***	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches supported with chromatograms, Raw data sheets, COA, summary data sheets etc. provided
6.	***3.2.P.8***	Documents for the procurement of API with approval from DRAP (in case of import).	Procurement details from M/s Atlas life sciences pvt Ltd C-1/360-361, G.I.D.C, estate, Odhav Ahmedabad-382 415, Gujrat, India is provided
7.	***3.2.P.8***	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
8.	***3.2.P.8***	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Decision: Deferred for submission of following:

- **Documents for the procurement of API with approval from DRAP (in case of import).**

- **Valid GMP certificate or DML of the drug substance manufacturer issued by relevant regulatory authority.**
- **Latest GMP inspection report of M/s Woodward Pakistan, conducted within last three years.**
- **Justification of the batch size of stability batches against the no. of units required for the completion of long-term stability studies data.**

1119.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharma Pvt Ltd. Lahore
	Name, address of Manufacturing site.	M/s CCL Pharma Pvt. Ltd. Plot 62 Quaid e Azam Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. N0; 33742 dated: 27.12.2021
	Details of fee submitted	PKR 30,000/-: dated 30/11/2021
	The proposed proprietary name / brand name	Lina Tablet 5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin……..5mg
	Pharmaceutical form of applied drug	Light pink colored, round biconvex shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, Dipeptidyl peptidase 4 (DPP4) inhibitors.
	Reference to Finished product specifications	Innovator
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trajenta Tablet 5mg by M/s Boehringer lngelheim, USFDA Approved.
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	New license granted on 13/05/2019 Tablet, Capsule, Syrup, Dry Powder Suspension Liquid Injectable & Dry Powder injectable section approved. Ref. letter no. 819 4 /2022-DRAP (Addl.Dire) dated 07.07.2022 The Firm has applied for GMP Inspection. The application is under processes at DRAP Office and inspection will be done as per availability of Area FID. The fimr's last GMP status is Compliant / Good.
	Name and address of API manufacturer.	M/s Fuxin Long Rui Pharmaceutical Co. ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Linagliptin is not present in Pharmacopoeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-20170427-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Trajenta 5mg Tablet by M/s West-Ward Columbus Inc., 1809 Wilson Road Columbus, Ohio 43228 USA by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Trajenta 5mg Tablet by M/s West-Ward Columbus Inc., 1809 Wilson Road Columbus, Ohio 43228 USA in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co. ltd, Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
API Lot No.	L-20200920-D01-L09-01
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.		T2-21	T3-21	T4-21
Batch Size		1500 tab	1500 tab	1500 tab
Manufacturing Date		03-2021	03-2021	03-2021
Date of Initiation		03-2021	03-2021	03-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the list of products previously approved with stability study data.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 23/08/2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.18985/20 dated 28/12/2020 is submitted wherein the permission to import API Linagliptin for the purpose of test/analysis and stability studies is granted. • Invoice No.HN201215-L dated 15/12/2020		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Remarks of Evaluator: Formulation and testing according to RRA and USP				
Decision: Approved. • **Registration letter will be issued after submission of latest inspection report valid within the last three years.** • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**				
1120.	Name, address of Applicant / Marketing Authorization Holder	Enzon Pharma Labs Pvt Ltd 5 km off Raiwind Manga Road, Lahore		
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5 km off Raiwind Manga Road, Lahore		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales		
	Dy. No. and date of submission	Dy. No. 6650 dated 10 March 2022		
	Details of fee submitted	PKR 30,000/-: dated 22 Feb 2022		
	The proposed proprietary name / brand name	Ensol-RLD Infusion (500ml)		

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100mL contains: Sodium Chloride…….....0.6%w/v Potassium Chloride……0.03%w/v Calcium Chloride Dihydrate…...0.02%w/v Sodium Lactate……...0.31%w/v Glucose Anhydrous ……...5.0%w/v
	Pharmaceutical form of applied drug	Intravenous Infusion
	Pharmacotherapeutic Group of (API)	Sodium Chloride: Other mineral supplements ATC CODE: A12CA01 Potassium Chloride: Other mineral supplements ATC CODE: A12BA01 Calcium Chloride Dihydrate: Electrolyte replacement ATC CODE: A12AA07 Sodium Lactate: Alkalinizing Agents ATC CODE: A14AB08 Glucose Anhydrous: Other IV Solution Additives ATC CODE: V06DC01
	Reference to Finished product specifications	USP
	Proposed Pack size	500mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lactated Ringer's and 5% Dextrose Injection, USP in VIAFLEX Plastic Container (USFDA)
	For generic drugs (me-too status)	Gee-sol RLD by M/S Gallop Water Sciences
	GMP status of the Finished product manufacturer	New License Approved. Last inspection conducted on 15 & 16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Sodium Chloride: Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China Potassium Chloride: Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China Calcium Chloride Dihydrate: Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China Sodium Lactate: Luoyang Longmen Pharmaceutical Co., Ltd County Industrial Zone, Luoning, Henan, China. Glucose Anhydrous: Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted relevant information against the Module III, including Process validation protocol, Finished product analytical method validation report & stability studies data of drug substance
	Stability studies	<u>Sodium Chloride:</u> Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (2871, 2872 and 2873) (METHOD BY TITRATION) <u>Potassium Chloride:</u> Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (KCL-054F, KCL-055B and KCL-056D) <u>Calcium Chloride Dihydrate:</u> Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CCL-253A, CCL- 253B and CCL-253C) <u>Sodium Lactate:</u> Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (151201, 151202 and 151203) <u>Glucose Anhydrous:</u> Stability study conditions: Real time: 30˚C ± 2˚C / 625% ± 25%RH for 60 months Accelerated: 40˚C ± 2˚C / 725% ± 25%RH for 6 months Batches: (W20150514, W20150515 and W20150516) (METHOD BY HPLC)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence is against Gee-So; RLD by M/S Gallop water science batch # 104015
	Analytical method validation/verification of product	Method verification studies has been submitted including linearity, accuracy, precision, specificity and robustness.

STABILITY STUDY DATA

Manufacturer of API	Sodium Chloride: Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China Potassium Chloride: Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China Calcium Chloride Dihydrate: Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China Sodium Lactate: Luoyang Longmen Pharmaceutical Co., Ltd County Industrial Zone, Luoning, Henan, China. Glucose Anhydrous: Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.		
API Lot No.	Sodium Chloride: 20200204 Potassium Chloride: 20200310 Calcium Chloride Dihydrate: 20200215 Sodium Lactate solution: 20010160 Glucose Anhydrous: 20200427-2		
Description of Pack (Container closure system)	500mL LDPE bottle w/ Eurocap		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A	B	C
Batch Size	400 L	400 L	400 L
Manufacturing Date	13-07-2020	13-07-2020	13-07-2020
Date of Initiation	14-07-2020	14-07-2020	14-07-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Ensol- NS 0.9% (25ml, 100ml, 500ml, 1000ml) Ensol- WFI (5ml, 10ml, 20ml) Ensol- 5% (100ml, 500ml, 1000ml) Ensol- DS (500ml, 1000ml) Ensol- RL (500ml, 1000ml)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sodium Chloride: Copy of DML Certificate (Certificate No. # 20160106) for Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China issued by China food & Drug Administration valid up to 03-12-2025 is submitted

		Potassium Chloride: Copy of DML Certificate (Certificate No. # 20150058) for Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China issued by China food & Drug Administration valid up to 15-12-2025 is submitted Calcium Chloride Dihydrate: Copy of DML Certificate (Certificate No. # 20150058) for Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China issued by China food & Drug Administration valid up to 15-12-2025 is submitted Sodium Lactate: Copy of DML Certificate (Certificate No. # 20190099) for Luoyang Longmen Pharmaceutical Co., Ltd County Industrial Zone, Luoning, Henan, China issued by China food & Drug Administration valid up to 29-11-2024 is submitted Glucose Anhydrous: Copy of GMP Certificate (Certificate No. # SD20180787) for Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China issued by China food & Drug Administration valid up to 14-10-2023 is submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy invoices for Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate and sodium lactate solution (invoice# HZA20CS88024 & invoice# LM2020031201) dated: 17-04-2020 & 07-04-2020 from Hangzhou Zhongbao Imp & Exp. Corp. Ltd, China & Luoyang Longmen Pharmaceutical Co., Ltd, China cleared by DRAP Lahore office dated 08-06-2020 & 18-06-2020. Glucose Anhydrous: Firm has submitted copy invoice (invoice# WFST312) dated: 28-04-2020 from Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China cleared by DRAP Lahore office dated 01-06-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator: Submitted data is in line with BP monograph.
In finish product the analysis of sodium is by atom spectrophotometer, potassium and calcium by flame photometry and lactate by HPLC, dextrose , chloride by titration method.
[1]

S. NO	Section	Deficiency	Reply
1.	1 .5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board.	The evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority is mentioned below as adopted by Board currently. https://www.accessdata.fda.gov/drugsatfda_docs /label/2017/016679s108lbl.pdf
2.	3.2.P.5	Control of drug product, specifications, provide the exact monograph of USP 42 which you are referring	The Control of Drug Product specifications is provided The exact monograph of USP 42 Volume 4, 2019 is available Analysis is according to USP
3.	3.2.P.5.2	Evidence of availability of atomic absorption spectrophotometer, flame photometer, polarimetry used in analysis	The evidence is in the form of the purchase invoice of atomic spectrophotometer, flame photometer and the polarimetry used in the analysis of the applied product.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will submit the details of container closure system whether with Euro cap or without Euro cap before issuance registration letter.**

1121.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceutical Private LTD Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Ltd Karachi Plot No K/201 S.I.T.E. (SHW) Phase II, Karachi,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14298 dated 13 June 2022
	Details of fee submitted	PKR 30,000/-: dated June 2022
	The proposed proprietary name / brand name	FLOXICAM 4mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated controlled released tablet contains: Lornoxicam …….8mg

	Pharmaceutical form of applied drug	White to yellowish round shaped film coated oral tablet
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Reference to Finished product specifications	Manufacturer's Spec
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xefo 8 mg Film-Coated Tablet, Takeda Austria GmbH, Austria approved.
	For generic drugs (me-too status)	Loxibar 8mg Tablet by M/s BARRETT HODGSON PAKISTAN (PVT) LTD
	GMP status of the Finished product manufacturer	New license granted on 22/02/2021 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	YUVRAJ CHEMICAL (PVT) LTD. Address: j-311, MIDC BHOSARI, PUNE -411 026 MAHARASHTRA, IDIA Tel: 91 20 46763934
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	No Official monograph of Lornoxicam is in any Pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (D10120001, D10120001, D10120003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is LoXIBAR 4mg tablet by M/s BARRETT HODGSON PAKISTAN

		(PVT) LTD by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LOXIBAR 4mg tablet by….. M/s BARRETT HODGSON PAKISTAN (PVT) LTD in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	YUVRAJ CHEMICAL (PVT) LTD. Address: j-311, MIDC BHOSARI, PUNE -411 026 MAHARASHTRA, IDIA Tel: 91 20 46763934		
API Lot No.	YLC/21005		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FL-001	FL-002	FL-003
Batch Size	1400 tab	1400 tab	1400 tab
Manufacturing Date	09 2021	09-2021	09-2021
Date of Initiation	11-09-2021	11-09-2021	V
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 6101996 issued by FDA India valid till 24/09/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The invoice number EXP/83 (21-22)dated 05-08-2021 for lornoxicam batch # YLC/21005 quantity 100 gm attested by AD Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted No 21 CFR software so not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator [VII]:

S No	Section #.	Deficiencies	Reply
1.	2.3.R.2	Justify the dispensing of drug substance for trial batch manufacturing without potency adjustment.	Adjustment as follow 4X100/potency=4x100/99.67=4.01 and we use 4.11 mg/tablet
2.	3.2.P.2.1.2	Povidone is used by the reference product while the applied formulation has no povidone as excipient. Clarification is required.	Povidone K30 is used as a binder in reference product as wellas in our product as binder Crosarmilose is used as disntigrent in RRA wherease we use primogel as distintigrent Cellulose microcrystalline is used in RRA where we are using avacil which is same
3.	3.2.P.2.2.1	CDP and pharmaceutical equivalence are not established against innovator product. Clarification is required	Pharmaceutical Equivalence have been established against the brand leader that is LoXIBAR 4mg tablet by M/s BARRETT HODGSON PAKISTAN (PVT) LTD by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LOXIBAR 4mg tablet by M/s BARRETT HODGSON PAKISTAN (PVT) LTD in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
4.		Documents for the procurement of API with approval from DRAP (in case of import).	The invoice number EXP/83 (21-22)dated 05-08-2021 for lornoxicam batch # YLC/21005 quantity 100 gm attested by AD Karachi.
5.	3.2.P.8.2	Provides stability study protocols	Provided
6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted No 21 CFR software so not applicable

Decision: Approved with innovator's specifications.

- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1122.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceutical Private LTD Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Ltd Karachi Plot No K/201 S.I.T.E. (SHW) Phase II, Karachi,
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1739 dated
	Details of fee submitted	PKR 30,000/-: dated June 2022
	The proposed proprietary name / brand name	FLOXICAM 8mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated controlled released tablet contains: Lornoxicam …….8mg
	Pharmaceutical form of applied drug	White to yellowish round shaped film coated oral tablet
	Pharmacotherapeutic Group of (API)	non-steroidal anti-inflammatory drug (NSAID)
	Reference to Finished product specifications	Manufacturer's Spec
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xefo 8 mg Film-Coated Tablet, Takeda Austria GmbH, Austria approved.
	For generic drugs (me-too status)	Loxibar 8mg Tablet by M/s BARRETT HODGSON PAKISTAN (PVT) LTD
	GMP status of the Finished product manufacturer	New license granted on 22/02/2021 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	YUVRAJ CHEMICAL (PVT) LTD. Address: j-311, MIDC BHOSARI, PUNE -411 026 MAHARASHTRA, IDIA Tel: 91 20 46763934
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	No Official monograph of Lornoxicam isin any Pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (D10120001, D10120001, D10120003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is LoXIBAR 4mg tablet by M/s BARRETT HODGSON PAKISTAN (PVT) LTD by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LOXIBAR 4mg tablet by….. M/s BARRETT HODGSON PAKISTAN (PVT) LTD in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	YUVRAJ CHEMICAL (PVT) LTD. Address: j-311, MIDC BHOSARI, PUNE -411 026 MAHARASHTRA, IDIA Tel: 91 20 46763934		
API Lot No.	YLC/21005		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FT-001	FT-002	FT-003
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	11-09-2021	11-09-2021	V
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 6101996 issued by FDA India valid till 24/09/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The invoice number EXP/83 (21-22)dated 05-08-2021 for lornoxicam batch # YLC/21005 quantity 100 gm attested by AD Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted No 21 CFR software so not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S No	Section #.	Deficiencies	Reply
1.	2.3.R.2	Justify the dispensing of drug substance for trial batch manufacturing without potency adjustment.	Adjustment as follow 4X100/potency=4x100/99.67=4.01 and we use 4.11 mg/tablet
2.	3.2.P.2.1.2	Povidone is used by the reference product while the applied formulation has no povidone as excipient. Clarification is required.	Povidone K30 is used as a binder in reference product as wellas in our product as binder Crosarmilose is used as disntigrent in RRA wherease we use primogel as distintigrent Cellulose microcrystalline is used in RRA where we are using avacil which is same
3.	3.2.P.2.2.1	CDP and pharmaceutical equivalence are not established against innovator product. Clarification is required	Pharmaceutical Equivalence have been established against the brand leader that is LoXIBAR 8mg tablet by M/s BARRETT HODGSON PAKISTAN (PVT) LTD by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LOXIBAR 4mg tablet by M/s BARRETT HODGSON PAKISTAN (PVT) LTD in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
4.		Documents for the procurement of API with approval from DRAP (in case of import).	The invoice number EXP/83 (21-22)dated 05-08-2021 for lornoxicam batch # YLC/21005 quantity 100 gm attested by AD Karachi.
5.	3.2.P.8.2	Provides stability study protocols	Provided

6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted No 21 CFR software so not applicable

Decision: Approved with innovator's specifications.

- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 02 Registration applications of drugs for which stability study data is submitted Registration applications for Form 5F

a) Form 5F Import (Human)

1123.	**Name, address of Applicant / Importer**	**M/s Al-Habib Pharmaceuticals, Plot #81, block B, SMCHS, Karachi.**
	Details of Drug Sale License of importer	DSL No.: 0230 Address: Al-Habib Pharmaceuticals, 81-B, block B, SMCHS, Karachi. Godown: 1. Plot No. 393/7 & 393/8 Sector 7-A KIA Karachi Validity: 18/05/2024 Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Laboratories IMA S.A.I.C, Palpa 2862, Ciudad Autonoma de Buenos Aires, Argentina.
	Name, address of manufacturer(s)	M/s Laboratories IMA S.A.I.C, Palpa 2862, Ciudad Autonoma de Buenos Aires, Argentina.
	Name of exporting country	Argentina
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**COPP:** Original legalized CoPP (certificate No. 191106) valid till 30-10-2021 issued by National Institute of Drugs, Argentina. The applied product is available for free sale in exporting country. The facilities and operations conform to WHO-GMP.
	Details of letter of authorization / sole agency agreement	Notarized copy of sole agency agreement is submitted whereby M/s Laboratories IMA S.A.I.C, authorizes M/s Al-Habib Pharmaceuticals to Import and commercialize different products including Gemcitabine 200 mg injection.
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 22752 Dated: 20-08-2021
	Details of fee submitted	PKR 100,000 Dated: 29-03-2021 Differential fee: PKR 50,000 Dated : 05-07-2021 (#98092840732), 100000 PKR, (#1954777) dated 29-03-2021
	The proposed proprietary name / brand name	**GEMSTAR 1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Gemcitabine HCl (as free base) ……. 1000 mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Anti-Cancer (Nucleoside) (L01BC05)
	Reference to Finished product specifications	USP
	Proposed Pack size	Type I amber glass 14 ml, 1 Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Gemzar® 1000mg injection (**USFDA** Approved) by Eli Lilly
	For generic drugs (me-too status)	Gemzar® 100mg injection by Eli Lilly Pakistan (Pvt) Ltd
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Hetero Labs Limited Survey.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ± 2°C. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product Gemzar® 1000mg injection by Eli Lilly (Batch # 1G00216-1)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I, amber glass vial 14 ml Bromobutyl elastomeric stopper. Aluminum capsule with flip off closure.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches 24 months real time stability data at 30°C ± 2°C / 70% ± 5%RH of 03 batches 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches (Batch# 34001/B, 34002/B, 34003/B)

Evaluation by PEC:

S No	Section #.	Deficiencies	Response
5.	**1.33**	Importer shall provide valid Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority in the country of origin and name of exporting country.	Original legalized CoPP (certificate No. 191106) valid till 30-10-2021 issued by National Institute of Drugs, Argentina. The applied product is available for free sale in exporting country. The facilities and operations conform to WHO-GMP. Firm submitted that "This get expired during its period in R& I that's why as per rule it will be considered as valid"
6.	**1.33**	The GMp of shanghai acebright pharma co ltd. China is provided as API manufacture but at some place Hetero Labs Limited Survey.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA is mentioned as API manufacturer clarification is needed in this regard.	Hetero Labs Limited Survey.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA is API manufacturer, its GMP is provided
7.	**1.33**	The GMP certificate of Laboratories IMA SAIC Argentina issued by National administration of drug, food and medical devices (ANMAT)is valid till 2 April 2021. Provides Valid GMP	The GMP certificate of Laboratories IMA SAIC Argentina issued by National administration of drug, food and medical devices (ANMAT) valid till 3 April 2022 is provided
8.	***2.3.S***	On API stability both IMA lab and hetro lab is mentioned justify	No justification is given

Decision: Deferred for following:

- **Clarification regarding the site wherein stability studies of drug substance have been performed, since in submitted stability sheets both IMA lab and Hetro lab is mentioned.**

1124.	Name, address of Applicant / Importer	M/s. Zam Zam Pharmaceutical, Karachi
	Details of Drug Sale License of importer	License No: 1205 Address: Suit no. 16 Beaumont Plaza, Beaumont Road, Karachi Validity: 15-FEB-2022. Status: License to sell drugs as distributor Renewal: Renewal application submitted on 14-Feb-2022.
	Name and address of marketing authorization holder (abroad)	POLİFARMA İLAÇ SAN. VE TİC. A.Ş. Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1, Ergene/TEKİRDAĞ/TURKEY
	Name, address of manufacturer(s)	POLİFARMA İLAÇ SAN. VE TİC. A.Ş. (Bulk Manufacturer) Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1, Ergene/TEKİRDAĞ/TURKEY AROMA İLAÇ SAN. LTD. ŞTİ (Primary and Secondary Packages) Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1, Kat: 2 Ergene/TEKİRDAĞ/TURKEY
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No.2021/1411) dated 29-04-2021 Republic of Turkey Ministry of health Turkish Medicines and Medical Devices Agency for 200/mg 20ml Emulsion for I.V Injection/Infusion. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. **The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP is valid till 29-04-2023.**
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from **POLİFARMA İLAÇ SAN. VE TİC. A.Ş**. The letter species that the manufacturer appoints **M/s Zam Zam Pharmaceutical** to register their products in Pakistan. The authorization letter is valid till **14-12-2025**.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Dy. No. 23850 Dated: 31-Aug-2021
	Details of fee submitted	PKR 150,000/-: 02-07-2021
	The proposed proprietary name / brand name	PROPOFOL-PF 1% 200mg/20ml emulsion for I.V. injection/infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of emulsion for injection/ infusion contains 10 mg of propofol as active ingredient.
	Pharmaceutical form of applied drug	Emulsion for injection or infusion. White coloured emulsion
	Pharmacotherapeutic Group of (API)	General Anaesthetic ATC-code: NOlAXlO
	Reference to Finished product specifications	European Pharmacopoeia
	Proposed Pack size	5x20ml ampoule in a box
	Proposed unit price	Rs 2400/-
	The status in reference regulatory authorities	Diprivan – Aspen Pharma – Ireland Fresenius Kabi – Austria
	For generic drugs (me-too status)	Propofol Abbot I.V. Injection, 10mg Each ml of emulsion for injection/ infusion contains 10 mg of propofol. Reg.no: 023142 20mlx5's – Rs 1367/=
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Bachem S.A Succursale De Vionnaz Route Du Simplon 22 CH-1895 Vionnaz Switzerland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ± 2°C 60% RH. The stability study data is till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	European Pharmacopoeia 20 mL, Type I, Clear, Glass Ampoule
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted (40ºC ± 2ºC), %75 ± 5 Humidity for 6 months. The real time stability study data is conducted at (30ºC ± 2ºC), % 65 ± 5 Humidity for 24 months. (Batch # A06110007A, A06110009A, A06110010A)

Evaluation by PEC:

The formulation is different from RRA
Certificate of Analysis (COA) of both drug substance(s) manufacturer and drug product manufacturer:
Stability data of 3 batches at accelerated and real time conditions:

S.#	Section #	Deficiencies	Zam Zam Reply
1	1.6.5	Valid Latest DSL which should have been provided for application.	Copy of valid DSL licence is attached along with renewal dated 14 feb 2022
2	1.33	Importer shall provide Certificate of Pharmaceutical Product (CoPP) / Free Sale Certificate issued by the relevant regulatory authority in the country of origin and name of exporting country.	**Original CoPP** # 29/04/2021 already provided with dossier valid till 29-04-2023, facility is GMP certified
3	1.5	Original, Legalized, and valid GMP of drug product manufacturer is required.	Original legalized and valid GMP of **POLIFARMA** was provided dated 31Aug.2021.
4	2.3.P.4	The excipients are different from the reference product justification is needed	The declaration letter is provided. PROPOFOL-PF 1% 200 mg/20 mL Emulsion for I.V. Injection/Infusion product is qualitatively and quantitatively equivalent to Propofol 1% Fresenius Anaesthetic Agent for Intravenous Injection or Infusion. The excipients contained in PROPOFOL-PF 1% 200 mg/20 mL Emulsion for I.V. Injection/Infusion are the same as reference product PROPOFOL 1% Fresenius Anaesthetic Agent for Intravenous Injection or Infusion
5	3.2.S.44	Certificate of Analysis (COA) of both drug substances(s) manufacturer and drug product manufacturer Stability Data of 3 batches at accelerated and real time conditions	Certificate of analysis for 3 different batches conducted by the API manufacturer and the finished product manufacturer to the Propofol API used in production by Polifarma İlaç are provided. The API manufacturer does not have to proceed stability study each batches that manufactured. The stability data of the batches produced by the API manufacturer within the scope of process validation are provided.
6	3.2.S.4.3	Analytical method Verification studies including specificity, accuracy, and repeatability (method precision)	Related substances and assay analytical method verification protocol and reports are provided

		performed by the Drug manufacturer drug substance (s) shall be submitted.	
7	3.2.S.7	The name on stability data of drug substance is not clear not indicating clearly that who is conducting this stability.	The up-to-date signed and stamped stability data of drug substance is provided by **BACHEM, Switzerland.**
8	3.2.P.3.5	Process validation reports including the protocols and results for critical process steps shall be provided.	Latest PVP and PVR are provided

Decision: Deferred for submission of Pharmaceutical equivalence studies against the innovator drug product.

Case No. 02 Registration applications of drugs for which stability study data is submitted Registration applications for Form 5F
d) Form 5F Deferred (Human)

1125.	Name, address of Applicant / Marketing Authorization Holder	M/s Indus Pharma Pvt. Ltd. Karachi Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan
	Name, address of Manufacturing site.	M/s Indus Pharma Pvt. Ltd. Karachi Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22213 dated 12th August, 2021
	Details of fee submitted	PKR 30,000/-: dated 16/06/2021
	The proposed proprietary name / brand name	Lecetam Injection 500mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Levetiracetam…….100mg
	Pharmaceutical form of applied drug	White to almost white powder
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Keppra Injection 500mg/5ml by M/s UCB Inc. USFDA approved
	For generic drugs (me-too status)	Lumark Injection 500mg/5ml by M/s The Searle Company Limited (Reg. no. 075873)
	GMP status of the Finished product manufacturer	GMP certificate issued on 28/11/2019 and valid for 2 years. Sterile Liquid (Injections,

		Ampoules & Infusions) section included in GMP certificate. (GMP status is updated, valid till 17/12/2023)
	Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The official monograph of Levetiracetam is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity Pyridin-2-ol, Levetiracetam acid, Levetiracetam related compound A, Any individual unspecified impurity & related compound B, Total impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (C5146-09-016, C5146-09-017, C5146-09-018)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, descriptions of manufacturing processes and controls, impurities, specifications, analytical procedure, and its verification studies, batch analysis and justification of specification, reference standard, container closure system, and stability studies of the drug product.
	Pharmaceutical equivalence	Pharmaceutical Equivalence has been established against the brand leader is Lerace Injection 500mg/5ml (Batch# 135069) by Hilton Pharma by performing quality tests (Description, Identification, Assay, pH of solution, Particulate matter,

		Extractable Volume, Sterility test, Bacterial Endotoxin test).
	Analytical method validation/verification of product	Method Validation studies have been submitted including System suitability, linearity, range, accuracy, precision, and specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Linhai, Zhejiang 317016, China		
API Lot No.	D5294-20-128R		
Description of Pack (Container closure system)	Printed clear glass ampoule of 5ml placed in a white opaque PVC tray. (1×5's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 (completed), 6 months (remaining) Real Time: 0, 3 (completed), 6, 9, 12, 18 and 24 months (remaining)		
Batch No.	TR-1/LVT 500mg/5ml	TR-2/LVT 500mg/5ml	TR-3/LVT 500mg/5ml
Batch Size	2000 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	11-01-2021	11-01-2021	11-01-2021
No. of Batches	03		

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by the concerned regulatory authority of the country of origin.	Copy of GMP certificate No. IT/E/API/10/2019 rev.1 issued by EudraGMP valid till 14/03/2022.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no: HH20201126R FTA Certificate no: P201479688170134 Batch no: D5294-20-128R Country of Origin: China DRAP AD Clearance date: 10-12-2020
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliant
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real-time and accelerated)	Submitted

Remarks OF Evaluator:

S. No	Section #	Observations/Deficiencies/Short-comings	Remarks of the firm
01	3.2.S.4.4	The submitted COA from drug substance manufacturer mentions the	The API and Finished product both were tested as per the pharmacopeia monograph

		reference for specs as USP but drug product manufacturer is claiming BP specification. Clarification is needed	of USP, for which the COA of API (tested by manufacturer) USP specification is provided
02	3.2.P.1	Composition is different from reference product of USFDA	Formulation of Lecetam injection 500mg/5 ml is as per the formulation of USFDA approved product "Kepra" which **i**s supplied in single-use 5 mL vials containing 500 mg levetiracetam, water for injection, 45 mg sodium chloride, and buffered at approximately pH 5.5 with glacial acetic acid and 8.2 mg sodium acetate trihydrate. KEPPRA injection must be diluted prior to intravenous infusion
03	2.3.P.2.5	Discussion of microbiological attributes of the Drug Product (e.g., preservative effectiveness studies to be performed as per recommendation of pharmacopoeia) not provided.	The preservative effectiveness study of Lecetam injection is not needed as the composuoj of the applied product is as per Kapra injecton (USFDA) and have no preservative
04	2.3.P.4	Control of excipients is missing	We have used Pharmacopeia standard excipients for which monographs and Analytical Procedures are attached, however for in-house excipient, analytical procedure is attached along with the COA of all excipients used in formulation.

Previous Decision: Deferred in 313
Deferred for the submission of microbiological attributes of the Drug Product i.e. complete 28-day preservative effectiveness study.

Response by Firm:
The preservative effectiveness study of Lecetam injection is not needed as the composition of the applied product is as per Kapra injection (USFDA) and have no preservative

Decision: Approved.

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

Agenda of Evaluator PEC-XI

Case No. 01: Registration applications of New Section of Human drugs on Form 5-F

a. M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore

The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has considered and approved the grant of following sections of **M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore** under Drug Manufacturing License No. 000779 (Formulation) vide approval letter No. F. 1-11/2009-Lic (Vol-I) dated 10th May, 2022.

S No.	Section
4.	Tablet Section II (General) **New**
5.	Dry Powder Suspension Section. **New**
6.	Dry Powder Sachet Section (General). **New**

Following applications have been submitted for registration by the firm.

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
	Name, address of Manufacturing site.	M/s Titlis Pharma (Private) Limited, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11040 dated 06/05/2022
	Details of fee submitted	PKR 30,000/-: dated 10/02/2022 (slip No#79520976505)
	The proposed proprietary name / brand name	Pentadol 75mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contain Tapentadol (as HCl) …….75mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	opioid analgesic
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1×10's, 2 ×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA (50mg, 75mg, 100mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Tapento IR 75mg tablet by M/s Sami Pharmaceuticals (Reg#093064)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt. Ltd., C-384, T.T.C. Industrial Area M.I.D.C., Pawane Village, Navi Mumbai 400 703, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for impurity & related substances, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months

		Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (6001012013, 6002012013, 6003022013)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Tapento 75mg Tablet by Sami Pharmaceuticals by performing quality tests (disintegration, weight variation, Assay, Dissolution, of dosage form). CDP has been performed against the same brand Tapento 75mg Tablet by Sami Pharmaceuticals in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Precise Chemipharma Pvt. Ltd., C-384, T.T.C. Industrial Area M.I.D.C., Pawane Village, Navi Mumbai 400 703, India		
API Lot No.	060007112020		
Description of Pack (Container closure system)	Yellow colored, round shaped, biconvex Film coated tablet, Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TP-01	TP-02	TP-03
Batch Size	666 tab	666 tab	666 tab
Manufacturing Date	Sep-2021	Sep-2021	Sep-2021
Date of Initiation	28-10-2021	28-10-2021	28-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**The firm has referred to previous inspection for authenticity of stability data of their product on the basis of which Registration Board in its 289th meeting held on 14-16th May, 2019 decided to approve registration of Delanso 30mg capsule and Delanso 60mg capsule.** **Inspection date: 02nd May, 2019** **The report shows that:** • **The firm have quaternary gradient HPLC (Shimadzu; Model; LC20AT); with time and date locked but it is not 21 CFR compliant.** • **Power backup by UPS and 200kv generator was available. Digital data logger was not installed for continuous monitoring and control of stability**

		chambers. Storage conditions were being recorded thrice daily manually.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted GMP certificate of M/s Precise Chemipharma Pvt. Ltd., C-384, T.T.C. Industrial Area M.I.D.C., Pawane Village, Navi Mumbai 400 703, India issued by Food & Drug Administration Marashtra State India valid upto 28-09-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice attested by AD I&E DRAP, Lahore dated 12-07-2021 **Invoice No. & date** / **Batch No.** / **Quantity Imported** **EXPS/00020224/ 2021-22 dated 05-07-2021** / 060007112020 / 1.4 kg The invoice is issued from M/s Precise Chemipharma Pvt. Ltd India in the name of M/s Titlis Pharma (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of all three batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
	• Firm has stated that they have R&D section as date of manufacturing of batches is September 2021 and grant of additional section is March 2022	
3.2.S.4	• You have proposed IR method for sample identification in specifications while stated performance by HPLC in specifications, clarify? • You have not included the tests for Solubility, loss on drying, melting point and chiral purity by HPLC in specification although these specifications are included in specifications by drug substance manufacturer, justify? • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted • Justification is required since mobile phase composition provided in chromatographic conditions for assay of drug substance by drug product manufacturer	• The firm submitted that we have performed the analysis of Tapentadol HCl as per BP Specifications • The firm further submitted that we have performed the analysis by both **FTIR & Liquid chromatography** and we are fully complaint with the BP testing method. Reports of tests are submitted. • The firm submitted that method of analysis for Tapentadol HCL is as per BP specifications; and we are fully complaint with the BP testing method. However, tests for enantiomeric purity also given in BP monograph while not included in specifications by drug product manufacturer. • Firm has submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance

	(orthophosphoric acid:methanol:water 0.1:35:65) is different from drug substance manufacturer(ammonium phosphate buffer adjust ph 6.3 with triethylamine: methanol 48:52)	• Drug substance manufacturer has performed the test as per in- hose (IH) specifications. • As this API (Tapentadol HCL) is in BP Pharmacopeia, so we have performed the analysis of Tapentadol HCL as per BP specifications; and we are fully complaint with the BP testing method. However, the ratio of mobile phase is different from BP monograph ~ ***mobile phaseA:*** *phosphoric* ***acid R, methanol R2, warer for*** *chromatography R* (0.1:10:90 *VIVIJ1);* ***- mobile phase B:*** *phosphoric* ***acid R, water for*** *chromatography R, methanal R2* (0.1:10:90 *VIVIJ1);*
3.2.P.2	• You have not performed CDP and pharmaceutical equivalence against the innovator brand justify? • Justification is required as your formulation contains Aerosil 200 (silicon dioxide) while innovator product does not contain this excipient?	• The firm submitted that as the innovator product is not registered in Pakistan therefore, Comparative dissolution profile of Pentadol 75mg Tablet was performed against the reference product Tapento IR 75mg Tablet Manufactured by Sami Pharmaceuticals (Pvt) Ltd. which is available in the market. • It is notable that the data of comparative dissolution profile report for Pentadol 75mg Tablet is remarkable and that the product is highly soluble and dissolves more than 85% within 15minutes in all three media (0.1 N HCl pH 1.2, Acetate buffer pH 4.5 and Phosphate buffer pH 6.8) at all sampling points. The results show that dissolution profile of test and reference products are almost similar. • Moreover, f2 calculations are not required. • Formulation of Pentadol 75mg Tablet is as similar as the formulation of innovator product except that it contains Aerosil 200 in its composition. • As per literature review and study of Hand Book for Pharmaceutical Excipients, it is notable that Aerosil 200 is an **inert excipient**, has compatibility with other excipients and active pharmaceutical ingredient of Pentadol 75mg tablet. Its safety and compatibility have also been established as no harsh / adverse effect has been observed in our stability studies.
3.2.P.5	• You have used USP apparatus II for dissolution studies instead of USP apparatus I as recommended by innovator product review document, justify?	• The firm submitted that initially we performed dissolution by using following parameters: **Media: 0.1N HCl (900ml), RPM: 75, Apparatus: II (Paddle), Time 30 min**. • The firm submitted all the dissolution parameters are same to innovator's specifications except for the dissolution apparatus.

- Stability batches were analyzed at 0, 3,& 6 months on in house testing but after reviewing the FDA drug approval /literature review **(FDA reviewing)**, we revised our testing method as follows:
Media: 0.1N HCl (900ml), RPM: 75, Apparatus: I (Basket), Time 30 min.

We develop the following protocol for stability studies

4. **To manufacture 3 new batches (Batch numbers: TP-07, TP-08 and TP-09) for performance of accelerated and long run stability testing as per innovator's specifications / dissolution parameters.**

- We have analyzed these batches as per innovator's specifications / dissolution parameters; and "0", 3rd month testing has been completed and results are complying with innovator specification. (Reports and chromatogram are submitted)

5. **To perform one month stress testing at 60℃ ± 2℃ / 75% ± 5% RH on samples of ongoing stability studies as per innovator's specifications / dissolution parameters.**

- We have drawn samples from our ongoing stability studies and kept them on stress conditions for one month (from 15th July - 2022 to 16th August - 2022); and analyzed that results are complying with innovator specification. (Reports and chromatogram are submitted)

6. **To perform the ongoing/long run stability studies of 9th month and other time intervals as per innovator's specifications / dissolution parameters.**

- We have performed 9th month stability studies as per innovator's specifications / dissolution parameters and analyzed that results are complying with innovator specification. (Reports and chromatogram are submitted)

- Moreover, we have performed 9th month stability study as per Titlis specifications and conclude that results are comparable. Results on both conditions are found similar and no impact observed in the results due to change in dissolution parameters. (Reports and chromatogram are submitted)

3.2.P.8	• Justification is required that 36 packs of tablets will be sufficient enough for performance of stability study till shelf life. • Justify the manufacturing of trial batches for stability study in September 2021 as approval of new section is granted on 17th & 18th March, 2022 and new section letter issuance date is 10-05-2022. • Submit documents for the procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	• We would like to submit that our batch size of Pentadol 75mg Tablets is 66 packs (666 tablets), whereas only 28.8 packs (288 tablets) are sufficient for the performance of stability study till the claimed shelf life (24 months). • Total sample size for accelerated stability study is 32 x 2 = 64 tablets .(Stability data sheet is attached) • Total sample size for long run stability study (24 months) is 32 x 7 = 224 tablets. (Stability data sheet is attached) • Total tablets is 64 + 224 = 288 tablets. • Firm has stated that they have R&D section and development of trial batches of Pentadol 75mg tablet was performed in our development (R&D) section. • The firm has submitted copy of form 6 No#10339/2021-DRAP dated 12-07-2021 from Precise Chem Pharma Pvt. Ltd., for the import of 1.4kg of tapentadol Hydrochloride attested by AD (I&E) DRAP Lahore. • The firm submitted that We have performed the stability study of Pentadol 75mg Tablet on our HPLC (QC-HPLC-001) SHIMAZDZU Model No. LC-20 AT, which is not 21CFR Compliant. • However, it is certified that **date and time of this HPLC (QC-HPLC-001) is locked and data alteration/editing is strictly restricted**. Moreover, this HPLC (QC-HPLC-001) has access control and only two authorized QC analysts have authorization to access and operate this HPLC (QC-HPLC-001). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is submitted
Decision: Approved with innovators specifications. • **Registration letter will be issued upon submission of CDP studies against the innovator/reference product.** • **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Case No. 02: Routine Registration applications of human drugs on Form 5-F

2.	Name, address of Applicant / Marketing Authorization Holder	ATCO Laboratories Limited., B-18, S.I.T.E., Karachi - 7500, Pakistan
	Name, address of Manufacturing site.	ATCO Laboratories Limited., B-18, S.I.T.E., Karachi -

		7500, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28455 Dated 15/ 10/ 2021
	Details of fee submitted	PKR 30,000/-: Dated 04/10/2021 (Deposit Slip#03634033378)
	The proposed proprietary name / brand name	Ondansetron Tablet 8mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron……..8mg (as Ondansetron Hydrochloride Dihydrate BP)
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Antiemetics and antinauseants, Serotonin (5-HT3) antagonists.
	Reference to Finished product specifications	USP
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran 8mg film coated tablet MHRA approved
	For generic drugs (me-too status)	Ongene 8mg Tablet by M/s High-Q Pharmaceuticals (Reg#091207)
	GMP status of the Finished product manufacturer	The firm was inspected on 22-03-2022 & 05-04-2022 by the panel for renewal of DML, regularization of section as per layout plan and additional sections and decision of panel is: Keeping in view the good facilities provided for manufacturing and quality control of pharmaceutical products registered in the name of firm being produced at the site and overall good maintenance of plan and the required documentation and SOPs, the panel recommended the grand of DML of the firm as well as regularization of sections as per layout plan and approval of additional sections
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bengaluru Rural District-561203 India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time:30˚C±2˚C/75% ± 5%RH Accelerated:40˚C±2˚C/75%±5%RH Stability of all three batches at accelerated conditions (AOND-17002, AOND-17003, AOND-17004) conducted for 06 months Real time stability study of two batches AOND-17002, AOND-17003, conducted for 36 months while real time stability study of one batch AOND-17004 conducted for 24 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Zofran 8mg Tablet by **GlaxoSmithKline Research Triangle Park, NC 27709** **Marketed by: Novartis Pharmaceuticals UK Limited** performing quality tests (Identification, Assay, Dissolution, disintegration). CDP of ondansetron 8mg tablets has been performed against the zofran 8mg tablets in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including range, accuracy, precision, specificity and robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India		
API Lot No.	AOND-20013		
Description of Pack (Container closure system)	ALU-ALU Blister pack packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MA089C	MA090C	MA091C
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	03/2021	03/2021	03/2021
Date of Initiation	25/03/2021	25/03/2021	25/03/2021
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of Rofl 500mcg tablet on the basis of which Registration Board in its 277th meeting dated 27-29 December, 2017 decided to approve registration of Rofl 500mcg tablet. Inspection date: 10-10-2017 The report shows that: The HPLC software is 21 CFR compliant. Adequate monitoring and control are available for stability chambers
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of GMP certificate #DCD/SPL.CL-1/CR-1510/2020-21 dated 06-02-2021 of M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bengaluru Rural District-561203 India valid upto one year from the date of issue. The firm has submitted copy of DML #DCD/MFG/Applicant Id-240 dated 26/06/2020 of M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India valid upto 13/02/2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice # OND1200 dated 10-11-2020 for import of 300gm of Ondansetron HCl Dihydrate Batch #AOND-20014, AOND-20012 and AOND-20013 in the name of M/s Atco Laboratories Ltd Karachi from M/s Anugraha Chemical India. ***However, the invoice is not attested by AD (I&E) DRAP field office***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	Valid GMP certificate issued by the relevant regulatory authority of country of origin of drug substance manufacturer shall be submitted	The firm has submitted valid copy of GMP certificate #DCD/SPL-1/CR-1733/2021-22 dated 31-01-2022 of M/s Anugraha Chemicals, D-47, D-48, D-49, D-50 and C-62, KSSIDC, Industrial Estate, Doddaballapur, India valid upto one year from the date of issue.
3.2.S.4	• Copies of the analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Firm has submitted copy of BP Monograph mentioning the test used for routine testing of the Drug substance / Active Pharmaceutical ingredient by Drug Product manufacturer. • Firm has submitted analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.

3.2.P.2	• Submit compatibility study as the qualitative composition of the applied formulation is not similar to innovator / reference product. Applied product: Zofran 8mg tab Lactose anhydrous: Lactose Sodium starch glycolate: Microcrystalline Cellulose Crospovidone: Pregelatinized maize starch Magnesium stearate: Magnesium Stearate, Opadry white: Methyl hydroxypropyl cellulose Purified water: Titanium dioxide (E171) Iron oxide (E172)	Firm has submitted drug excipient compatibility study and the results show that insignificant variation occurs during compatibility studies. Hence it is concluded that drug is compatible with excipients.
3.2.P.5.1	Justification for finished product specifications of USP is required as the drug substance has been analysed as per BP specifications by M/s Atco Laboratories. ***(drug substance manufacturer given both BP & USP specifications)***	The firm submitted that initially at the time of development, we have started the material and product development according to British pharmacopeia monograph. During the development of product, we found that the drug release of both test and reference sample is greater than 85% within 15 minutes in comparison studies while the time limit mentioned in BP was 45 minutes. We switched to more stringent specification for our products and complies with USP specifications which states that "NLT 80% (Q) of the labeled amount of $C_{18}H_{19}N_3O$ is dissolved in 15 minutes".
3.2.P.8	Submit documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EXP-018 dated 17-08-2021 from M/s Anugraha Chemicals India in the Name of Atco Laboratories Ltd for import of 180gm of Ondansetron Hydrochloride dihydrate batch No AOND-21007 attested by AD (I&E) DRAP Karachi dated 05-09-2021. ***The batch No. of API is different from that submitted in batch analysis of drug substance and stability summary sheets. Furthermore the date of manufacturing of API mentioned in invoice is June 2021 and attestation date of AD (I&E) DRAP Karachi is 5/09/2021 while manufacturing of finished product is 03/2021.***

Decision: Deferred for clarification since batch No. of API mentioned in invoice attested by AD (I&E) DRAP is different from that mentioned in batch analysis of drug substance, BMR and stability summary sheets of drug product

3.	Name, address of Applicant / Marketing Authorization Holder	ATCO Laboratories Limited., B-18, S.I.T.E., Karachi - 7500, Pakistan
	Name, address of Manufacturing site.	ATCO Laboratories Limited., B-18, S.I.T.E., Karachi - 7500, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30933 Dated 11/ 11/ 2021
	Details of fee submitted	PKR 30,000/-: Dated 04/10/2021 (Deposit Slip#65306391198)
	The proposed proprietary name / brand name	Ondansetron Syrup 4mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ondansetron……..4mg (as Ondansetron Hydrochloride Dihydrate BP)
	Pharmaceutical form of applied drug	Syrup
	Pharmacotherapeutic Group of (API)	Antiemetics and antinauseants, Serotonin (5-HT3) antagonists.
	Reference to Finished product specifications	USP
	Proposed Pack size	5ml, 15ml, 25ml, 50ml, 60ml, 100ml, 120ml.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Syrup 4 mg/5 ml MHRA approved
	For generic drugs (me-too status)	Dysit 4mg/5ml Syrup by M/s Wimits Pharmaceuticals (Reg#096447)
	GMP status of the Finished product manufacturer	The firm was inspected on 22-03-2022 & 05-04-2022 by the panel for renewal of DML, regularization of section as per layout plan and additional sections and decision of panel is: Keeping in view the good facilities provided for manufacturing and quality control of pharmaceutical products registered in the name of firm being produced at the site and overall good maintenance of plan and the required documentation and SOPs, the panel recommended the grand of DML of the firm as well as regularization of sections as per layout plan and approval of additional sections
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No D-47 to D-50, and C-62 to C-63, KSSIDC, Industrial Estate, Doddaballapur, Bengaluru Rural District-561203 India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug substance.
	Stability studies	Stability study conditions: Real time:30˚C±2˚C/75% ± 5%RH Accelerated:40˚C±2˚C/75%±5%RH Stability of all three batches at accelerated conditions (AOND-17002, AOND-17003, AOND-17004) conducted for 06 months Real time stability study of two batches AOND-17002, AOND-17003, conducted for 36 months while real time stability study of one batch AOND-17004 conducted for 24 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Onseron 4mg/5ml syrup by M/s Indus Pharma (Pvt.) Ltd by performing quality tests (description, Identification, pH, Assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including range, accuracy, precision, specificity and robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India		
API Lot No.	AOND-20013		
Description of Pack (Container closure system)	Amber glass bottle packed in printed carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FE074C	MA077C	MA088C
Batch Size	2000ml	2000ml	2000ml
Manufacturing Date	05/03/2021	05/03/2021	05/03/2021
Date of Initiation	17/03/2021	17/03/2021	17/03/2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of Rofl 500mcg tablet on the basis of which Registration Board in its 277th meeting dated 27-29 December, 2017 decided to approve registration of Rofl 500mcg tablet. Inspection date: 10-10-2017 The report shows that: The HPLC software is 21 CFR compliant. Adequate monitoring and control are available for stability chambers

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of GMP certificate #DCD/SPL.CL-1/CR-1510/2020-21 dated 06-02-2021 of M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bengaluru Rural District-561203 India valid upto one year from the date of issue. The firm has submitted copy of DML #DCD/MFG/Applicant Id-240 dated 26/06/2020 of M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India valid upto 13/02/2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice # OND1200 dated 10-11-2020 for import of 300gm of Ondansetron HCl Dihydrate Batch #AOND-20014, AOND-20012 and AOND-20013 in the name of M/s Atco Laboratories Ltd Karachi from M/s Anugraha Chemical India. ***However, the invoice is not attested by AD (I&E) DRAP field office***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	Valid GMP certificate issued by the relevant regulatory authority of country of origin of drug substance manufacturer shall be submitted	The firm has submitted valid copy of GMP certificate #DCD/SPL-1/CR-1733/2021-22 dated 31-01-2022 of M/s Anugraha Chemicals, D-47, D-48, D-49, D-50 and C-62, KSSIDC, Industrial Estate, Doddaballapur, India valid upto one year from the date of issue.
3.2.S.4	• Copies of the analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Firm has submitted copy of BP Monograph mentioning the test used for routine testing of the Drug substance / Active Pharmaceutical ingredient by Drug Product manufacturer. • Firm has submitted analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.
3.2.P.2	• Submit compatibility study as the qualitative composition of the applied formulation is not similar to innovator / reference product. Applied product: Zofran 4mg/5ml syrup Citric acid monohydrate: Citric acid Sodium citrate dihydrate: Sodium citrate dihydrate	• Firm has submitted drug excipient compatibility study and the results show that insignificant variation occurs during compatibility studies. Hence it is concluded that drug is compatible with excipients. • Firm submitted that Pharmaceutical equivalence studies of test formulation against locally available approved formulation has been performed due to unavailability of innovator product in Pakistan with reference to "Decision of

	Sodium benzoate — Sodium benzoate Liquid Sorbitol — Sorbitol solution Sodium Saccharin — ------ Liquid Glucose — -------- Banana Flavour — Strawberry flavour (contains ethanol*) Purified water — Purified water • Justification is required since pharmaceutical equivalence have not been conducted against the innovator product.	307th and 308th meeting of Drug Registration Board"
3.2.P.5.1	Justification for finished product specifications of USP is required as the drug substance has been analysed as per BP specifications by M/s Atco Laboratories. ***(drug substance manufacturer given both BP & USP specifications)***	The firm submitted that initially at the time of development, we have started the material and product development for tablet dosage form according to British pharmacopeia monograph. Once the material has been established as per BP Specification, parallel development of syrup dosage form started. The syrup formulation is only available in United States Pharmacopeia so we have to develop the specifications of Ondansetron Syrup 4mg/5mL as per USP monograph.
3.2.P.8	Submit documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EXP-018 dated 17-08-2021 from M/s Anugraha Chemicals India in the Name of Atco Laboratories Ltd for import of 180gm of Ondansetron Hydrochloride dihydrate batch No AOND-21007 attested by AD (I&E) DRAP Karachi dated 05-09-2021. ***The batch No. of API is different from that submitted in batch analysis of drug substance and stability summary sheets. Furthermore the date of manufacturing of API mentioned in invoice is June 2021 and attestation date of AD (I&E) DRAP Karachi is 5/09/2021 while manufacturing of finished product is 03/2021.***
Decision: Deferred for clarification since batch No. of API mentioned in invoice attested by AD (I&E) DRAP is different from that mentioned in batch analysis of drug substance, BMR and stability summary sheets of drug product		
4.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore,
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25925 dated 17-09-2021

	Details of fee submitted	PKR 30,000/-: dated 13-08-2021
	The proposed proprietary name / brand name	"Amacure oral granules USP 4mg"
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Montelukast sodium……4mg
	Pharmaceutical form of applied drug	Oral granule is a white granular coarse free-flowing, homogeneous solid with no extraneous particles packaged in polyethylene aluminium / polyester sachet which finally packed in unit carton. Each unit carton contain 10 sachet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Singulair (4mg) oral granules USFDA Approved
	For generic drugs (me-too status)	Moncid Sachet by M/s De-Mont Research Laboratories (Reg# 084056)
	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 06-07-2020 based on inspection conducted on 04-03-2020
	Name and address of API manufacturer.	M/s Dhanuka Laboratories Limited., Keshwana, Rajput, Kotputli, Shahpura, Jaipur-303108 Rajhastan India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MLS-F#009/15, MLS-F#010/15, MLS-F#011/15)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the Montiget sachet by Getz pharma by performing quality tests (Appearance and assay)

		Firm has submitted CDP report of their applied product against Montiget sachet 4mg by Getz pharma in Acid media (pH 1.2), acetate Buffer (pH 4.5) & 0.5% sodium dodecyl sulphate solution. The values for f2 is in the acceptable range
	Analytical method validation/verification of product	Firm have submitted method verification studies including accuracy, precision and specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Dhanuka Laboratories Limited., Keshwana, Rajput, Kotputli, Shahpura, Jaipur-303108 Rajhastan India		
API Lot No.	MTS-2104004		
Description of Pack (Container closure system)	Amacure oral granule is a white granular coarse free-flowing, homogeneous solid with no extraneous particles packaged in alu-alu sachet packets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T01	T02	T03
Batch Size	2000 Sachets	2000 Sachets	2000 Sachets
Manufacturing Date	04-01-2021	06-01-2021	08-01-2021
Date of Initiation	09-01-2021	09-01-2021	09-01-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of GMP certificate #DC/A-2/WHO GMP/2019/35 dated 17-01-2019 of M/s Dhanuka Laboratories Limited., Keshwana, Rajput, Kotputli, Shahpura, Jaipur-303108 Rajhastan India valid 16-01-2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice # SO/KE/2122/0011 dated 22-04-2021 for import on 5kg of Montelukast sodium Batch #MTS-2104004 attested by AD (I&E) DRAP Lahore on 30-04-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm have submitted Data of stability batches supported by attested respective documents like chromatograms and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit. Strength of Active ingredient shall be stated clearly. In case API is in	The firm submitted that in formulation of Amacure Oral Granules 4mg, Sachet, Montelukast is used as active ingredient. Where it is present with salt sodium. In batch formula it is clearly mentioned "4mg

	the form of salt, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.	Montelukast is equal to 4.160mg of Montelukast sodium"
1.6.5	• Submit valid GMP certificate of drug substance manufacturer	The firm have submitted copy of GMP certificate #DC/A-2/WHO-GMP/2022/77 dated 27-01-2022 of M/s Dhanuka Laboratories Limited., SP4-4, Industrial Area, Keshwana, Rajput, Kotputli, Shahpura, Jaipur-303108 Rajasthan India issued by Drug Control Organization Rajasthan India valid for three years from the date of issue.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies is provided
3.2.S.5	• The title of reference standard Montelukast Sodium does not relate with lot No. R035A0. Clarify? • The submitted COA of working standard for batch No#WS/19/003 mentions both limits for Montelukast Sodium and Montelukast Dicyclohexylamine in assay test, clarify?	The firm submitted that as per USP monograph of Amcure sachet oral granules Montelukast Dicyclohexamine Reference standard used for testing and we follow same. ***The firm didn't give clarification how they submitted assay test results for two different salts against the same standard***
3.2.P.2	• Details of comparator product including batch numbers, mfg & expiry date in pharmaceutical equivalence are required to be provided • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph (dissolution, identification, uniformity of dosage unit. • You have not performed Pharmaceutical equivalence of the applied drug with the innovator / product, justify?	• The firm have submitted details of comparator product. Montiget Sachet by M/s Getz Pharma Batch No. 686D03 Mfg date; July 2020 Expiry date; July 2022 • The firm submitted that we have done all testing of both product (Amcure sachet and Montiget Sachet), it was just human error that complete results are not listed. The firm have submitted complete analysis report with comparator. • The firm submitted that innovator product Singulair Paediatric 4mg Granule by Organon Pharma UK was not available in market and DRAP give us relaxation to do equivalence studies with me-too product
3.2.P.5	• Test for uniformity of dosage unit (content uniformity) and dissolution is not included in specifications and not performed in batch analysis although given in USP monograph of drug product, clarify? • The copies of complete analysis of at least two batches shall be provided. • Provide details of analytical columns used in analytical procedure • The title of reference standard Montelukast Sodium does not relate with lot No. R035A0. Clarify? • The submitted COA of working standard for batch No#WS/19/003 mentions both limits for Montelukast Sodium and Montelukast	• The firm have submitted that we have done complete testing as per USP monograph; it was a human error that complete results are not listed. The firm submitted revised finished product specifications results • Firm has submitted copies of complete analysis of three trail batches • The firm submitted revised analytical procedure containing details of analytical column • The firm stated that submitted certificate of analysis of working standard is placed in product dossier by mistake, as we receive both COA's from vendor. The certificate of analysis received from manufacturer with working standard has both assay test limits.

	Dicyclohexylamine in assay test, clarify?	***However same COA has been submitted by the firm*** • The submitted certificate of analysis is correct as manufacturer of API done testing of both forms of API collectively. But we use Montelukast sodium in our product for manufacturing. The COA received from manufacturer with working standard has both assay test limits.
3.2.P.8	• Stability data reflect that test for identification, dissolution test and uniformity of dosage unit has not been performed at initial time point and throughout stability studies at both accelerated and real time conditions, justify? • The limits for assay test in stability study data is mentioned as 90%-110% instead of 90%-108% as mentioned in USP monograph, clarify? • Submit COA, Raw data sheets & analytical record of stability studies containing calculation formula for both assay & dissolution test • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required. • Submit latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) • Th API was imported on 30-04-2021 while the batches were manufactured in 01-2021 before the import of API, justify the manufacturing of batches before import of API	• ***The firm has submitted revised stability summary sheets containing all test at each time points and conditions.*** • The firm submitted that al results are within limits, the term written in specifications was just a copy past error and submitted revised stability summary sheets. • The firm has submitted raw data sheet containing calculation formula for both assay & dissolution test. ***However, the firm has not submitted COA and analytical record of all batches during stability study. Raw data sheets show that the results of dissolution tests are different than that reported in summary sheets.*** • Audit trail reports on product testing is submitted • Latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) is not submitted • The firm submitted Letter No. 4233/202/DRAP-AD-CD(I&) dated 20-03-2020 for ***"permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies"*** containing Montelukast sodium 5kg issued AD (I&E) DRAP Lahore

Decision: Deferred for following:

- **Submission of Scientific justification for use of Montelukast sodium as reference standard in analytical procedures instead of Montelukast dicyclohexylamine specified by USP monograph.**
- **Submission of COA and analytical record of all batches during stability study.**
- **Clarification since the results of dissolution test mentioned in Raw data sheets are different than that reported in summary sheets.**
- **Justification is required since the submitted copy of commercial invoice # SO/KE/2122/0011 dated 22-04-2021 has been attested by AD (I&E) DRAP Lahore dated 30-04-2021 for import of 5kg of Montelukast sodium Batch #MTS-2104004 while trial batches have been manufactured in January 2021**.

Case No; 03; Withdrawal Registration application

a. Withdraw of application for registration of drugs of New DML M/s Swera Pharmaceuticals Rawat Islamabad

The firm submitted a request dated 14-09-2022 and humbly stated that we have submitted data for Mepra 40mg Injection CTD Dossier upto 3rd month stability data dated 11-01-2022. We are withdrawing the complete application of Mepra 40mg injection and submitting new application with full fee challan No. 802460765103 and stability data of new batch numbers i.e. RD-1003 and RD-1004. So kindly consider batch No. RD-1003 and RD-1004 batch number for evaluation. 6th month stability data submitted RD-1003 and RD-1004

5.	Name, address of Applicant / Marketing Authorization Holder	M/s Swera Pharmaceuticals., Plot No. 27, Street No. S-4, National Industrial Zone Rawat-Islamabad

	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals., Plot No. 27, Street No. S-4, National Industrial Zone Rawat-Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1011 dated 11/01/2022
	Details of fee submitted	PKR 30,000/-: dated 04/01/2022 (Deposit Slip#99432398)
	The proposed proprietary name / brand name	MEPRA 40mg I.V Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Omeprazole Sodium (Sterile Lyophilized Powder 38%)…….……40mg
	Pharmaceutical form of applied drug	I.V Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40 mg Powder for Solution for Infusion MHRA Approved
	For generic drugs (me-too status)	Teph 40mg Infusion by M/s Sami Pharmaceuticals, (Reg#057830)
	GMP status of the Finished product manufacturer	New DML granted on 13th September 2021
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd., Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad
Decision: Registration Board Acceded the request of firm and decided to reject the application		

b. Withdraw of application for registration of drugs of New DML M/s Swera Pharmaceuticals Rawat Islamabad

The firm submitted a request dated 14-09-2022 and humbly stated that we have submitted data for Emozol 40mg Injection CTD Dossier upto 3rd month stability data dated 11-01-2022. We are withdrawing the complete application of Emozol 40mg injection and submitting new application with full fee challan No. 8510651844 and stability data of new batch numbers i.e. RD-1001 and RD-1002. So kindly consider batch No. RD-1001 and RD-1002 batch number for evaluation. 6th month stability data submitted RD-1001 and RD-1002.

6.	Name, address of Applicant / Marketing Authorization Holder	M/s Swera Pharmaceuticals., Plot No. 27, Street No. S-4, National Industrial Zone Rawat-Islamabad
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals., Plot No. 27, Street No. S-4, National Industrial Zone Rawat-Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1010 dated 11/01/2022
	Details of fee submitted	PKR 30,000/-: dated 04/01/2022 (Deposit Slip#317820239848)
	The proposed proprietary name / brand name	Emozol 40mg I.V Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Esomeprazole Sodium (Sterile Lyophilized Powder 36%)…….……40mg
	Pharmaceutical form of applied drug	Lyophilized Sterile powder for Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXIUM I.V. 40mg for injection USFDA Approved
	For generic drugs (me-too status)	Nexum IV 40mg Injection by M/s Getz Pharma, (Reg#050651)
	GMP status of the Finished product manufacturer	New DML granted on 13th September 2021
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd., Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad
Decision: Registration Board Acceded the request of firm and decided to reject the application		

Case No. 04: New cases for registration of Human Drugs on Form 5 (Local)

7.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Velbeta Cream 0.1% w/w
	Composition	Each gm contains: Betamethasone as Valerate……1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13034 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Corticosteroids
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	5gm, 10gm, 15gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Audavate 0.1% w/w Cream MHRA approved
	Me-too-status	Betso 1mg Cream (0.1%) by M/s Linta Pharmaceuticals (Reg#100690)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. vetnovate cream 0.1% w/w (cover letter), velbeta cream 0.1% w/w (form 5), vetnovate (betamethasone as valerate) (fee challan)

		• The firm submitted that brand name velbeta cream 0.1% w/w proposed in form-5 is for the formulation of betamethasone as valerate cream. • Dosage form is not mentioned on fee challan • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section • The R&I date of application was 05-03-2019 while date mentioned on form 5 was 06-04-2019, clarification was taken from firm. The firm clarified that date on form 5 was mistakenly mentioned as 06-04-2019
	Decision: Approved.	
8.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Velbeta N Cream 0.1% +0.5% w/w
	Composition	Each gm contains: Betamethasone as Valerate……0.1% (1mg) Neomycin Sulphate……0.5% (5mg)
	Dairy No. date of R &I fee	Form-5 Dy.No 13031 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Corticosteroids, Combinations With Antibiotics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5gm, 10gm, 15gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Betnovate N Cream MHRA approved
	Me-too-status	Betso-N Cream by M/s Linta Pharmaceuticals (Reg#100691)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Vetnovate-N cream 0.1%+0.5% w/w (cover letter), Velbeta N cream 0.1%+0.5% w/w (form 5), Vetnovate-N (betamethasone+neomycine) (fee challan) • The firm submitted that brand name Velbeta N cream 0.1%+0.5% w/w proposed in form-5 is for the formulation of betamethasone+neomycine cream. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section • Dosage form is not mentioned on fee challan
	Decision: Approved with innovator's specifications **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
9.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Cefinir Capsule 500mg
	Composition	Each Capsule Contains: Cefdinir……..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13032 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Third-generation cephalosporins
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; As per SRO

	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm provided evidence of applied product in RRA, Omnicef capsule 300mg, USFDA Approved **(**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**).** However, the applied strength is different from the provided evidence of product in RRA. • The firm provided evidence of me-too. Efdir Capsules 300mg by M/s Shrooq Pharmaceuticals (Reg# 057376). ***However, the applied strength is different from the provided evidence of me-too.*** • The firm submitted letter No. F. 1-37/93-Lic (Vol.I) (M-215) dated 29th January 2009 issued by Deputy drugs controller (L&A) showing presence of Capsule (Cephalosporin)
	Decision: Deferred for following points: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
10.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Cpine Injection 250mg
	Composition	Each Vial Contains Cefepime as HCl with L Arginine eq. to Cefepime.…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13028 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Fourth-generation cephalosporins
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Cefstar Injection IV/IM 250mg by M/s Barrett Hodgson Pakistan (Reg#076005)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm provided evidence of applied product in RRA, Maxipime for injection (500mg, 1g, 2g) USFDA Approved. However, the applied strength is different from the provided evidence of product in RRA. • The firm have mentioned different names on cover letter, form 5 and fee challan. oncef injection 250mg (cover letter), Cpine injection 250mg (form 5), oncef / cefipime injection (fee challan) • The firm submitted that brand name Cpine injection 250mg proposed in form-5 is for the formulation of cefipime 250mg injection. • Strength of applied product not mentioned on fee challan • The firm submitted letter No. F. 1-37/93-Lic dated 03/08/2015 issued by secretary CLB showing presence of Dry powder injectable (Cephalosporin) • The firm provided justification for addition of overage in formulation and stated that 3% overage used in formulation

		are to cover the loss during different steps of manufacturing process • The firm have mentioned the use of type II glass vial as primary packaging material of the applied formulation
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
11.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Climycin T Gel 1.2% + 0.025%w/w
	Composition	Each gm contains: Clindamycin Phosphate……..1.2% (12mg) Tretinoin……..0.025% (0.25mg)
	Dairy No. date of R &I fee	Form-5 Dy.No 13038 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Anti-Acne Preparations
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	20gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	VELTIN Gel (1.2%/0.025%) USFDA approved
	Me-too-status	Clinoin Gel 1.2% + 0.025% by M/s Hudson Pharma (Reg#097120)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Veltin gel 1.2%+0.025% w/w (cover letter), Climycin T gel 1.2%+0.025% w/w (form 5), Veltin / clindamycin phosphate;tretinoin gel (fee challan) • The firm submitted that brand name Climycin T gel 1.2%+0.025% w/w proposed in form-5 is for the formulation of clindamycin phosphate;tretinoin gel. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section
	Decision: Approved with innovator's specifications. **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
12.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Dicanal Gel 1% w/w
	Composition	Each Gram Contains: Diclofenac Diethylamine eq to Diclofenac Sodium..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13024 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	NSAIDs
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	20gm, 25gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac 1% Gel MHRA approved
	Me-too-status	Mobil-N gel by M/s Davis Pharmaceutical (Reg#089593)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. V Phonac gel 1%, (cover letter),

		Dicanal gel 1% w/w (form 5), Phonac / Diclofenac Diethylamine eq to Diclofenac Sodium gel (fee challan) • The firm submitted that brand name Dicanal gel 1% w/w proposed in form-5 is for the formulation of Diclofenac Diethylamine eq to Diclofenac Sodium. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section
	Decision: Approved.	
13.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Rotaver Injection 40mg/2ml
	Composition	Each 2ml Contains: Drotaverine HCl……40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13020 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2mlx25's; As per SRO
	Approval status of product in Reference Regulatory Authorities	1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI **Hungary** Approved) (Link: https://www.ogyei.gov.hu/gyogyszeradatbazis&action=show_details&item=11235) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD **Romania** Approved) (Link: https://www.anm.ro/_/_RCP/RCP_6973_10.10.14.pdf) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, **Bulgaria** Approved) (Link: http://www.bda.bg/images/stories/documents/register/drugs/details/lf2120.htm)
	Me-too-status	Hi-Spa 40mg/2ml injection by M/s Helix Pharma (Reg#073604)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Span injection 40mg/2ml (cover letter), Rotaver injection 40mg/2ml (form 5), Span / Drotaverine HCl Inj (fee challan) • The firm submitted that brand name Rotaver injection 40mg/2ml proposed in form-5 is for the formulation of Drotaverine HCl. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Liquid Injectable (Ampoule/Vial) (General and General Antibiotic) Section • The firm have submitted complete manufacturing outline mentioning terminal sterilization
	Decision: Approved with innovator's specifications. **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
14.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Conaflo Capsule 150mg

	Composition	Each Capsule Contains: Fluconazole…….150mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13030 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Imidazole and triazole derivatives
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Diflucan 150mg hard capsules MHRA approved
	Me-too-status	Flucoaid Capsule 150mg by M/s Aspin Pharma (Reg#100136)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Flucap capsule 150mg (cover letter), Conaflu capsule 50mg (form 5), Flucap / Fluconazole cap (fee challan) • The firm submitted that brand name Conaflu capsule 50mg proposed in form-5 is for the formulation of Fluconazole. • The R&I date of application was 05-03-2019 while date mentioned on form 5 was 06-04-2019, clarification was taken from firm. The firm clarified that date on form 5 was mistakenly mentioned as 06-04-2019
	Decision: Approved.	
15.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Tri-Glo Cream
	Composition	Each gram contains: Fluocinolone Acetonide……..…0.01% (0.1mg) Hydroquinone……..…4% (40mg) Tretinoin…….0.05% (0.5mg)
	Dairy No. date of R &I fee	Form-5 Dy.No 13026 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Anti-Acne Preparations For Topical Use
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	15gm, 30gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRI-LUMA (fluocinolone acetonide, hydroquinone, tretinoin) cream, (0.01%/4%/0.05%) USFDA approved
	Me-too-status	Troika Cream by M/s ARP (Pvt) Ltd (Reg# 099219)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Skinalar cream (cover letter), Tri-Glo cream (form 5), Skinalar / Fluocinolone Acetonide, Hydroquinone, Tretinoin cream (fee challan) • The firm submitted that brand name Tri-Glo cream proposed in form-5 is for the formulation of Fluocinolone Acetonide, Hydroquinone, Tretinoin. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section • The firm did not provide justification for addition of 2% overage • The R&I date of application was 05-03-2019 while date mentioned on form 5 was 06-04-2019, clarification was

		taken from firm. The firm clarified that date on form 5 was mistakenly mentioned as 06-04-2019
	Decision: Approved with innovator's specifications with change of brand name. • **Registration letter shall be issued after submission of justification for addition of 2% overage** • **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
16.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Feroxy Injection 50mg/ml
	Composition	Each ml Contains: Iron (as Ferric Carboxymaltose)……..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13021 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Haematinic
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	10ml ampoule; As per SRO
	Approval status of product in Reference Regulatory Authorities	INJECTAFER (50mg iron/mL) (750mg iron/15ml, 500mg iron/10ml) for intravenous use (vial) USFDA approved
	Me-too-status	Ferinject Injectable 500mg/10ml vial by M/s RG Pharmaceutical (Reg#072548)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Iryjet injection 50mg/ml (cover letter), Feroxy injection 50mg/ml (form 5), Iryjet / Iron As Ferric Carboxymaltose (fee challan) • The firm submitted that brand name Feroxy injection 50mg/ml proposed in form-5 is for the formulation of Iron As Ferric Carboxymaltose. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Liquid Injectable (Ampoule/Vial) (General and General Antibiotic) Section • The firm have submitted complete manufacturing outline mentioning terminal sterilization • The firm have mentioned the use of type I primary packaging material for applied formulation
	Decision: Approved.	
17.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Conatra Capsule 100mg
	Composition	Each Capsule Contains: Itraconazole (as Immediate Release Pellets)…..…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13029 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Triazole derivatives
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	4's; As per SRO
	Approval status of product in Reference Regulatory Authorities	SPORANOX 100mg Capsules MHRA approved
	Me-too-status	Fewnol 100mg Capsule by M/s Dew-Max Pharmaceuticals (Reg#095507)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021

	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Itralfa capsule 100mg (cover letter), Conatra Capsule 100mg (form 5), Itralfa / Itraconazole capsule (fee challan) • The firm submitted that brand name Conatra Capsule 100mg proposed in form-5 is for the formulation of Itraconazole. • Submit undertaking at the end of form 5 duly signed by the technical persons • Source of pellets, along with stability studies data of pellets of three batches as per zone IV-A, COA, valid GMP certificate of supplier of pellets and differential fee in case of import of pellets is not submitted
	Decision: Approved with innovator's specifications. • **Registration letter shall be issued after submission of Source of pellets, along with stability studies data of pellets of three batches as per zone IV-A, COA, valid GMP certificate of supplier of pellets and differential fee in case of import of pellets and related documents.** • **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
18.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Ketorol Injection 30mg/ml
	Composition	Each ml Contains: Ketorolac Tromethamine…….30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13018 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TORADOL Injection (15mg/ml, 30mg/ml) USFDA approved. **Discontinued** **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Xevolac 30mg/ml Injection by M/s Danas Pharmaceuticals (Reg#099867)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Analac injection 30mg/ml (cover letter), Ketorol injection 30mg/ml (form 5), Analac / Ketorolac trometamol inj (fee challan) • The firm submitted that brand name Ketorol injection 30mg/ml proposed in form-5 is for the formulation of Ketorolac Tromethamine. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Liquid Injectable (Ampoule/Vial) (General and General Antibiotic) Section • The firm have submitted complete manufacturing outline mentioning terminal sterilization • The firm have mentioned the use of type I primary packaging material for applied formulation • The firm have not provided clarification for addition of 5% overage of API in master formulation.
	Decision: Registration Board deferred the case for further deliberation regarding the sterilization method of the applied formulation whether by way of terminal sterilization or	

	otherwise. Moroever firm shall submit justification for addition of 5% overage of API in master formulation.	
19.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Linocaine Jelly 2%
	Composition	Each gram contains: Lignocaine HCl 21.3mg eq to Lignocaine HCl Anhydrous……20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13039 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Local anesthetics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	15gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Lignopharm Gel 2% by M/s E-Pharm Laboratories (Reg#092768)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Migno gel 2% w/w (cover letter), Linocaine jelly 2% w/w (form 5), Migno / Lignocaine gel (fee challan) • The firm submitted that brand name Linocaine jelly 2% w/w proposed in form-5 is for the formulation of Lignocaine 2%. • Submit undertaking at the end of form 5 duly signed by the technical persons • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section • The firm provide evidence of applied product in RRA. Xylocaine 2% jelly TGA Approved. It contains lidocaine (lignocaine) hydrochloride 20mg/g. The label claim should be revised as per reference formulation
	Decision: Approved with following label claim: **Each gram contains:** **Lignocaine HCl ……20mg** **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/ change of hydrated factor and adjustment of weight of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
20.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Dantron Injection 8mg/4ml
	Composition	Each 4ml Contains: Ondansetron (as HCl Dihydrate)……8mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13019 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Antiemetics and Antinauseants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	4mlx5's, 4mlx1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 8mg/4ml Solution for Injection MHRA Approved

	Me-too-status	Vemtix 8mg/4ml Injection by M/s Biolabs (Pvt) Ltd (Reg#093252)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Anset injection 2mg/ml (cover letter), Dantron injection 8mg/4ml (form 5), Anset / Ondansetron as HCl Dihydrate inj (fee challan) • The firm submitted that brand name Dantron injection 8mg/4ml proposed in form-5 is for the formulation of Ondansetron as HCl Dihydrate. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Liquid Injectable (Ampoule/Vial) (General and General Antibiotic) Section • The firm have submitted complete manufacturing outline mentioning terminal sterilization
	Decision: Approved.	
21.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Permeth Cream 5%
	Composition	Each Gram Contains: Permethrin……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13033 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Ectoparasiticides, Incl. Scabicides, Insecticides And Repellents
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	30gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Permethrin 5% w/w Cream MHRA approved
	Me-too-status	Nixcal Cream 5% w/w by M/s Caliph Pharmaceuticals (Reg#096915)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Delice cream 5% w/w (cover letter), Permith cream 5%, (form 5), Delice / Permithrin cream (fee challan) • The firm submitted that brand name Permith cream 5% proposed in form-5 is for the formulation of Permithrin. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section • The R&I date of application was 05-03-2019 while date mentioned on form 5 was 06-04-2019, clarification was taken from firm. The firm clarified that date on form 5 was mistakenly mentioned as 06-04-2019
	Decision: Approved with innovator's specifications. • **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
22.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Lorcin Injection 40mg/0.04mg/4ml

	Composition	Each 4ml Contains: Pholoroglucinol hydrate……40mg (corresponding to anhydrous Phloroglucinol…31.12mg) Trimethylphloroglucinol……0.04mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13022 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Musculotropic Antispasmodic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	4mlx6's; As per SRO
	Approval status of product in Reference Regulatory Authorities	SPASFON, solution for injection in ampoule by M/s TEVA HEALTH, (ANSM Approved)
	Me-too-status	Gluwix Injection by M/s Wnsfield Pharmaceuticals (Reg#093652)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Spatri injection 31.12mg+0.04mg/4ml (cover letter), Lorcin injection 40mg/0.04mg/4ml (form 5), Spatri / hydrated Pholoroglucinol, Trimethylphloroglucinol (fee challan) • The firm submitted that brand name Lorcin injection 40mg/0.04mg/4ml proposed in form-5 is for the formulation of Pholoroglucinol, Trimethylphloroglucinol. • Dosage form on fee challan is not mentioned • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Liquid Injectable (Ampoule/Vial) (General and General Antibiotic) Section • The firm have submitted complete manufacturing outline mentioning terminal sterilization
	Decision: Approved with innovator's specifications. • **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
23.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Oxicam Gel 0.5% w/w
	Composition	Each Gram Contains: Piroxicam…….5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13023 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	NSAIDs
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	25gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Feldene 0.5% w/w Gel MHRA approved
	Me-too-status	Inflavan Gel 0.5%w/w by M/s Evolution Pharmaceuticals (Reg#095400)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Trost gel 0.5% w/w (cover letter), Oxim / oxicam gel 0.5% w/w (form 5), Trost / Piroxicam gel (fee challan) • The firm submitted that brand name Oxicam gel 0.5% w/w proposed in form-5 is for the formulation of Piroxicam.

		• The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section
	Decision: Approved.	
24.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Tacromus ointment 0.1% w/w
	Composition	Each Gram Contains: Tacrolimus (as Monohydrate)……1mg (0.1% w/w)
	Dairy No. date of R &I fee	Form-5 Dy.No 13025 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Agent for dermatitis, excluding corticosteroids
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10gm, 30gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Protopic (0.03%, 0.1%) ointment USFDA approved
	Me-too-status	Graftil 0.1% Ointment by M/s Biolabs (Pvt) Ltd (Reg#096755)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Remus 0.1% ointment (cover letter), Tacromus ointment 0.1% w/w (form 5), Remus / Tacrolimus (as Monohydrate) ointment (fee challan) • The firm submitted that brand name Tacromus ointment 0.1% w/w proposed in form-5 is for the formulation of Tacrolimus (as Monohydrate). • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section
	Decision: Approved with innovator's specifications. • **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
25.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Bina Cream 1% w/w
	Composition	Each gram Contains: Terbinafine HCl……..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13027 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Antifungal for topical use
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	5gm, 10gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	LAMISIL 1% w/w Cream MHRA approved
	Me-too-status	LMS 1% Cream by M/s Rotex Pharma (Reg#097429)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Telfin cream 1% w/w (cover letter), Bina cream 1% w/w (form 5), Telfin / Terbinafine cream (fee challan)

		• The firm submitted that brand name Bina cream 1% w/w proposed in form-5 is for the formulation of Terbinafine. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Cream/Ointment/Gel (General) Section
	Decision: Approved.	
26.	Name and address of manufacture / Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd. 13-km, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form and Strength	Trama Injection 100mg/2ml
	Composition	Each 2ml Contains: Tramadol HCl…….100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 13017 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Opioids Analgesic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRAMAL tramadol hydrochloride 100mg/2mL injection ampoule TGA Approved
	Me-too-status	Amadrol Injection 100mg/ 2ml by M/s Amarant Pharmacetuicals (Reg#83042)
	GMP Status	GMP certificate issued to the firm on 25-05-2021 based on inspection conducted on 13-04-2021
	Remark of the Evaluator [XI]	• The firm have mentioned different names on cover letter, form 5 and fee challan. Ramadol injection 100mg/2ml (cover letter), Trama injection 100mg/2ml (form 5), Ramadol / Tramadol HCl inj (fee challan) • The firm submitted that brand name Trama injection 100mg/2ml proposed in form-5 is for the formulation of Tramadol HCl. • The firm submitted letter No. F. 1-37/93-Lic dated 03.08.2015 issued by Secretary Central Licensing Board confirming the presence of Liquid Injectable (Ampoule/Vial) (General and General Antibiotic) Section • The firm have revised the weight of API in master formulation as 100mg/2ml instead of 105mg/2ml as per the applied label claim. • The firm have submitted complete manufacturing outline.
	Decision: Approved with innovator's specifications. • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change of weight of API in the master formulation and product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

Case No. 05: Deferred cases:

a. Deferred cases of Human drugs on Form 5 F:

27.	Name, address of Applicant / Marketing Authorization Holder	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20556 dated 28-07-2021
	Details of fee submitted	Rs.30,000/- dated 16-06-2021
	The proposed proprietary name / brand name	Gluset 10mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Empagliflozin …. 10 mg
	Pharmaceutical form of applied drug	Oral solid dosage form
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors ATC code: A10BK03
	Reference to Finished product specifications	In-House
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JARDIANCE (10mg, 25mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Diampa Tablet 25 mg by M/s Getz Pharma (Reg#093073)
	GMP status of the Finished product manufacturer	The firm have submitted GMP certificate issued on 25-04-209 based on inspection conducted 07-03-2019.
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 24 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. (Batch No. 20160606, 20161017, 20161219)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical Equivalence Studies of the applied product against the reference product of "Diampa 10 mg Tablet" by M/s Getz pharma. CDP has been performed against the same brand that "Diampa 10 mg Tablet" by Getz pharma in HCl buffer Acetate Buffer pH 4.5 and Phosphate buffer pH 6.8. The values for f2 are in the acceptable range.
	Analytical method validation / verification of product	Firm has submitted verification/ validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of APIs	Fuxin Long Rui Pharmaceutical Co., Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China		
API Lot No.	L-E-20200409-D01-E06-01		
Description of Pack (Container closure system)	Alu-PVC blisters sealed with Aluminium foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% HR ±5% Accelerated: 40°C ± 2°C / 75% HR ±5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24, (Months)		
Batch No.	SEG00109P	SEG00209P	SEG00309P
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	09/2020	09/2020	09/2020
Date of Initiation	22-09-2020	22-09-2020	22-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Refer to previous onsite inspection report of their product Esmelin tablet 15mg dated 10-08-2020 on the basis of which Registration Board in its 313th meeting decided to approve the registration of Esmelin 15mg tablet. The report shows that: • The HPLC software is 21 CFR compliant and Log of data was available in the HPLCs. The data was also checked through hard copies of chromatograms. • Adequate monitoring and control were available for stability chamber. The firm was advised to improve the alarm system.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China issued on dated: 24/08/2020, valid till 23/08/2023 by Liaoning Fuxin Management Committee – China is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice attested by AD I&E DRAP, Lahore.

Invoice No.	Batch No.	Quantity Imported	Date of approval by DRAP
SY2006 1201-F	L-E-20200409-D01-E06-01	0.35 kg	26-06-2020

		The invoice is issued from M/s Shenyang Vast Pharm-Tech Co., Ltd China and it does not contain the name of manufacturer.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted supporting document including summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4- 1.3.5	• Submit copy of valid drug manufacturing license • Provide evidence of required manufacturing facility	• The firm have submitted copy of DML issued on 22-07-2015 and renewal of DML applied on 13-07-2020. • *The firm have submitted panel inspection report dated* 13-04-2017 for renewal on DML showing presence of Tablets (General, Antibiotic, Anti-TB, Psychotropic) section
1.4.1	• You have applied for a new drug product while the applied product is generic drug product, clarify?	• The firm submitted that it is a typographical mistake and we applied for generic drug product and submitted corrected form 5F
1.5.15-1.5.20	• Commitments submitted without signature	• The firm have submitted signed commitments as per module-I
3.2.S.4.3	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted
3.2.S.5	• The firm have submitted COA of Reference Standards or Materials which was expired on 18.04.2018. Justification is required for using expired working standard	• The firm submitted that this reference standard was use in the analysis of stability batches of drug substance. So, it was not expired at that time. COA of drug substance is submitted. ***However, the firm did not submit COA of the reference standard that was used in analysis of drug substance.***
3.2.P.1	• You have used Povidone K-30 instead of hydroxypropyl cellulose used by innovator product and not performed compatibility study, clarify? • Pharmaceutical equivalence of the applied drug with the innovator product is not performed, justify?	• The firm have submitted compatibility study report. The firm have performed compatibility study through binary mixture approach and assessed through HPLC. The samples were stored at 25ºC/60% and 40ºC/75% in both open and closed container for 1month. *However, compatibility report of only 40ºC/75% RH open container is submitted and compatibility report 40ºC/75% closed container and 25ºC/60% in both open and closed container is not submitted*

		• The firm submitted that innovator product was not available so they use reference product for pharmaceutical equivalence studies.
3.2.P.2.2.1	• Justify the CDP studies at 50 rpm, since the innovator product review documents specifies 75 rpm for dissolution studies.	• *The firm submitted that in FDA dissolution guidance 2018, CDP studies is at 50 rpm, but we also perform at 75 rpm and submitted revised CDP report.*
3.2.P.5.1	• Justify the acceptance criteria of dissolution test i.e. NLT 70% (Q) in 30min since FDA review documents specifies that dissolution criteria shall be NLT Q in 15 min and BP/USP/Ph. Int specifies that Q should not be less than 75%. • Justification is required as the registration board in its 293rd meeting decided that For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator /reference product with reference to dissolution specification will not be acceptable. • Test for identification, degradation products, content uniformity and microbial quality not included in specifications although included by innovator's product, justify? • Justify the dissolution studies at 50 rpm, since the innovator product review documents specifies 75 rpm for dissolution studies.	• *The firm submitted that it is a typographical mistake, the acceptance criteria of dissolution test is NLT 80% in 30 min as per FDA dissolution guidance 2018. And our batches results are more that 100%. However, FDA review documents specifies that dissolution criteria shall be NLT Q in 15 min* • We are assuring that we do not variate from innovator / reference product with reference to dissolution specifications • *The firm submitted that we also performed these tests and also updated the specifications*. However, test for degradation products are not performed. Updated SOP and COA of the product is submitted • *The firm submitted that in FDA dissolution guidance 2018, CDP studies is at 50 rpm, but we also perform at 75 rpm and submitted revised CDP report.*
3.2.P.5.3	• In validation of analytical procedure Methanol 45; buffer 55 is mentioned as the mobile phase while in analytical procedure ACN 45; buffer 55 is mentioned as mobile phase, Clarify?	• The firm submitted that it is a typographical mistake, no methanol is used, ACN is used as per analytical procedure and submitted revised validation of analytical procedure report.
3.2.P.6	Justify the use of Reference Standards or Materials from M/s Clearsynth Labs Ltd India since drug substance manufacturer is Fuxin Long Rui Pharmaceutical Co., Ltd china.	• The firm stated that we use Reference Standards or Materials from Fuxin Long Rui Pharmaceutical Co., Ltd for testing. The use of M/s Clearsynth Labs reference standard is only for comparison purpose. *However, the firm did not submit COA of Reference Standards or Materials from Fuxin Long Rui Pharmaceutical Co., Ltd*
3.2.P.8	• Submit documents for procurement of API, since the submitted invoice does not specify the details of manufacturer • Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required. • Submit chromatograms, raw data sheets & COAs of the conducted stability study with proper separator so that the data can be evaluated	• *The firm submitted that only distributor name is mentioned in invoice but Batch no. and expiry date of product is mentioned.* • The firm submitted copy of DML certificate No. Liao20150233, dated: 21/12/2017 valid till 20/12/2022, issued by Food & Drug Administration of Liaoning Province- China. • The firm have submitted chromatograms, raw data sheets of the conducted stability study. *The COAs are still not submitted. Chromatograms of assay at initial time point is still not submitted. Submitted*

	• Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Submit Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	*chromatogram not readable. Raw data sheet of accelerated stability study at 3rd month time point is not submitted* • *The lambda given in chromatogram is 225/224nm while lambda mentioned in analytical procedure is 210nm.* • *The firm have submitted declaration of software quality form Agilent for HPLC software 21CFR. However, the firm have not submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.* • The firm have submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers at real time conditions. *Record of Digital data logger for temperature & humidity monitoring of stability chambers at accelerated conditions is not submitted*	

Decision of 316the meeting of DRB:

Deferred for following:

- Submission of COA of the reference/working standard that was used in analysis of drug substance.
- Justification of the acceptance criteria of dissolution test i.e. NLT 70% (Q) in 30min since FDA review documents specifies that dissolution criteria shall be NLT Q in 15 min
- Submission of COA of Reference/Working Standards from Fuxin Long Rui Pharmaceutical Co., Ltd.
- Submission of COAs and readable copies of Chromatograms of assay at initial time point.
- Submission of Raw data sheet of accelerated stability study at 3rd month time point
- Clarification regarding variation in the lambda wavelength specified in analytical procedure from that mentioned on chromatograms.
- Submission of Compliance Record of HPLC software 21CFR & audit trail reports on product testing for complete stability studies
- Submission of Record of Digital data logger for temperature & humidity monitoring of stability chambers at accelerated conditions
- Submission fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Evaluation by PEC:

- Firm has submitted COA of working standard
- Firm submitted that Dissolution criteria Q=80% in 30 minutes according to FDA guidelines, in our document it was a typographical error and submitted updated SOP for analysis and revised specifications. ***However, FDA review documents of innovator product specifies that dissolution criteria shall be NLT Q in 15 min***
- Firm has submitted COA of Working Standards from Fuxin Long Rui Pharmaceutical Co., Ltd.
- Firm has submitted readable copies of Chromatograms of assay at initial time point. ***However, COA at initial time point is not submitted***
- Firm has submitted Raw data sheet of accelerated stability study at 3rd month time point
- The firm has submitted updated SOP for analysis containing same lambda / wavelength as mentioned on chromatograms
- Firm has submitted a certificate of HPLC software 21CFR compliance. ***However, audit trail reports on product testing for complete stability studies is not submitted***
- Record of Digital data logger for temperature & humidity monitoring of stability chambers at accelerated conditions is submitted
- Firm has submitted Fee Rs. 7,500/- on deposit slip No. 55298427798 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Decision: Approved with innovator's specifications.

- **Registration letter shall be issued after submission of revised dissolution specifications of *NLT Q in 15 min* of applied product as per innovator's product**
- **Submission of batch analysis certificate of initial time point of all stability batches, as per submitted analytical record**
- **Submission of audit trail reports on product testing for complete stability studies**

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

28.	Name, address of Applicant / Marketing Authorization Holder	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20557 dated 28-07-2021
	Details of fee submitted	Rs.30,000/- dated 16-06-2021
	The proposed proprietary name / brand name	Gluset 25 mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Empagliflozin …. 25 mg
	Pharmaceutical form of applied drug	Oral solid dosage form
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors ATC code: A10BK03
	Reference to Finished product specifications	In-House
	Proposed Pack size	10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JARDIANCE (10mg, 25mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Diampa Tablet 25 mg by M/s Getz Pharma (Reg#093074)
	GMP status of the Finished product manufacturer	The firm have submitted GMP certificate issued on 25-04-209 based on inspection conducted 07-03-2019.
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III (Drug Substance):	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 24 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. (Batch No. 20160606, 20161017, 20161219)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical Equivalence Studies of the applied product against the reference product of "Diampa 25 mg Tablet" by M/s Getz pharma. CDP has been performed against the same brand that is "Diampa 25 mg Tablet" by Getz pharma in HCl buffer, Acetate Buffer pH 4.5 and Phosphate buffer pH 6.8. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted verification/ validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of APIs	Fuxin Long Rui Pharmaceutical Co., Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China		
API Lot No.	L-E-20200409-D01-E06-01		
Description of Pack (Container closure system)	Alu-PVC 110 mm blisters sealed with Aluminium foil		
Stability Storage Condition	Real time: 30ºC ± 2ºC / 65% HR ±5% Accelerated: 40ºC ± 2ºC / 75% HR ±5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24, (Months)		
Batch No.	SEP00109P	SEP00209P	SEP00309P
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	09/2020	09/2020	09/2020
Date of Initiation	22-09-2020	22-09-2020	22-09-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Refer to previous onsite inspection report of their product Esmelin tablet 15mg dated 10-08-2020 on the basis of which Registration Board in its 313th meeting decided to approve the registration of Esmelin 15mg tablet. The report shows that: • The HPLC software is 21 CFR compliant and Log of data was available in the HPLCs. The data was also checked through hard copies of chromatograms. • Adequate monitoring and control were available for stability chamber. The firm was advised to improve the alarm system.

<table>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China issued on dated: 24/08/2020, valid till 23/08/2023 by Liaoning Fuxin Management Committee – China is submitted.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of commercial invoice attested by AD I&E DRAP, Lahore.
<table>
<tr><th>Invoice No.</th><th>Batch No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>SY20061201-F</td><td>L-E-20200409-D01-E06-01</td><td>0.35 kg</td><td>26-06-2020</td></tr>
</table>
The invoice is issued from M/s Shenyang Vast Pharm-Tech Co., Ltd China and it does not contain the name of manufacturer.</td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>The firm has submitted supporting document including summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Not submitted</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td>Not submitted</td></tr>
</table>

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4-1.3.5	• Submit copy of valid drug manufacturing license • Provide evidence of required manufacturing facility	• The firm have submitted copy of DML issued on 22-07-2015 and renewal of DML applied on 13-07-2020. • The firm have submitted panel inspection report dated 13-04-2017 for renewal of DML showing presence of Tablets (General, Antibiotic, Anti-TB, Psychotropic) section
1.4.1	• You have applied for a new drug product while the applied product is generic drug product, clarify?	• The firm submitted that it is a typographical mistake and we applied for generic drug product and submitted corrected form 5F
1.5.6	• The firm have claimed In house specifications and the product is not available in any pharmacopeia	• ***No reply submitted***
1.5.15-1.5.20	• Commitments submitted without signature	• The firm have submitted signed commitments as per module-I
3.2.S.4.3	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted
3.2.S.5	• The firm have submitted COA of Reference Standards or Materials which was expired on 18.04.2018. Justification is required for using expired working standard	• The firm submitted that this reference standard was use in the analysis of stability batches of drug substance. So, it was not expired at that time. COA of drug substance is submitted. ***However, the firm***

		did not submit COA of the reference standard that was used in analysis of drug substance.
3.2.P.1	• You have used Povidone K-30 instead of hydroxypropyl cellulose used by innovator product and not performed compatibility study, clarify? • Pharmaceutical equivalence of the applied drug with the innovator product is not performed, justify?	• The firm have submitted compatibility study report. The firm have performed compatibility study through binary mixture approach and assessed through HPLC. The samples were stored at 25ºC/60% and 40ºC/75% in both open and closed container for 1month. ***However, compatibility report of only 40ºC/75% RH open container is submitted and compatibility report 40ºC/75% closed container and 25ºC/60% in both open and closed container is not submitted*** • The firm submitted that innovator product was not available so they use reference product for pharmaceutical equivalence studies.
3.2.P.2.2.1	• Justify the CDP studies at 50 rpm, since the innovator product review documents specifies 75 rpm for dissolution studies.	• ***The firm submitted that in FDA dissolution guidance 2018, CDP studies is at 50 rpm, but we also perform at 75 rpm and submitted revised CDP report.***
3.2.P.5.1-3.2.P.5.2	• Justify the acceptance criteria of dissolution test i.e. NLT 70% (Q) in 30min since FDA review documents specifies that dissolution criteria shall be NLT Q in 15 min and BP/USP/Ph. Int specifies that Q should not be less than 75%. • Justification is required as the registration board in its 293rd meeting decided that For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator /reference product with reference to dissolution specification will not be acceptable. • Test for identification, degradation products, content uniformity and microbial quality not included in specifications although included by innovator's product, justify? • Justify the dissolution studies at 50 rpm, since the innovator product review documents specifies 75 rpm for dissolution studies.	• ***The firm submitted that it is a typographical mistake, the acceptance criteria of dissolution test is NLT 80% in 30 min as per FDA dissolution guidance 2018. And our batches results are more that 100%. However, FDA review documents specifies that dissolution criteria shall be NLT Q in 15 min*** • We are assuring that we do not variate from innovator / reference product with reference to dissolution specifications. Our product dissolution results are within limits of innovator specifications. • ***The firm submitted that we updated the specifications as per innovator's specifications***. However, test for degradation products are not performed. Updated SOP and COA of the product is submitted • ***The firm submitted that in FDA dissolution guidance 2018, CDP studies is at 50 rpm, but we also perform at 75 rpm and submitted revised CDP report.***
3.2.P.5.3	• In validation of analytical procedure Methanol 45; buffer 55 is mentioned as the mobile phase while in analytical procedure ACN 45; buffer 55 is mentioned as mobile phase, Clarify?	• The firm submitted that it is a typographical mistake, no methanol is used, ACN is used as per analytical procedure and submitted revised validation of analytical procedure report.
3.2.P.6	Justify the use of Reference Standards or Materials from M/s Clearsynth Labs Ltd India since drug substance manufacturer is Fuxin Long Rui Pharmaceutical Co., Ltd china.	• The firm stated that we use Reference Standards or Materials from Fuxin Long Rui Pharmaceutical Co., Ltd for testing. The use of M/s Clearsynth Labs reference standard is only for comparison purpose. ***However, the firm did not submit COA of Reference Standards or Materials from Fuxin Long Rui Pharmaceutical Co., Ltd***

3.2.P.8	• Submit documents for procurement of API, since the submitted invoice does not specify the details of manufacturer • Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required. • Submit chromatograms, raw data sheets & COAs of the conducted stability study with proper separator so that the data can be evaluated • Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Submit Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated) • The quantity of imported drug substance as per submitted invoice is 0.35kg and three batches of 25mg gluset tablets and 10mg gluset tablets each of 5000 tablets were manufactured from it. Justification is required as how the imported drug substance was sufficient enough to manufacture three batches of each strength. • The total quantity required for manufacturing of three batches of both strength is 0.525kg while imported drug substance is 0.35kg	• ***The firm submitted that only distributor name is mentioned in invoice but Batch no. and expiry date of product is mentioned.*** • The firm submitted copy of DML certificate No. Liao20150233, dated: 21/12/2017 valid till 20/12/2022, issued by Food & Drug Administration of Liaoning Province- China. • The firm have submitted chromatograms, raw data sheets of the conducted stability study. ***The COAs are still not submitted. Chromatograms of assay at initial time point is still not submitted. Submitted chromatogram not readable. Raw data sheet of accelerated stability study at 3rd month time point is not submitted*** • ***The lambda given in chromatogram is 225/224nm while lambda mentioned in analytical procedure is 210nm.*** • ***The firm have submitted declaration of software quality form Agilent for HPLC software 21CFR. However, the firm have not submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.*** • The firm have submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers at real time conditions. ***Record of Digital data logger for temperature & humidity monitoring of stability chambers at accelerated conditions is not submitted*** • The firm submitted that we import more material to fulfil the required batch quantity. • The firm has submitted another copy of commercial invoice attested by AD I&E DRAP, Lahore. **Invoice No.** | **Batch No.** | **Quantity Imported** | **Date of approval by DRAP** **SY200714-F** | L-E-20200409-D01-E06-01 | 0.75 kg | 27-07-2020 The invoice is issued from M/s Shenyang Vast Pharm-Tech Co., Ltd China and it does not contain the name of manufacturer

Decision of 316th meeting of DRB:

Deferred for following:

- Submission of COA of the reference/working standard that was used in analysis of drug substance.
- Justification of the acceptance criteria of dissolution test i.e. NLT 70% (Q) in 30min since FDA review documents specifies that dissolution criteria shall be NLT Q in 15 min
- Submission of COA of Reference/Working Standards from Fuxin Long Rui Pharmaceutical Co., Ltd
- Submission of COAs and readable copies of Chromatograms of assay at initial time point.
- Submission of Raw data sheet of accelerated stability study at 3rd month time point
- Clarification regarding variation in the lambda wavelength specified in analytical procedure from that mentioned on chromatograms.
- Submission of Compliance Record of HPLC software 21CFR & audit trail reports on product testing for complete stability studies
- Submission of Record of Digital data logger for temperature & humidity monitoring of stability chambers at accelerated conditions

• Submission fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
Evaluation by PEC: • Firm has submitted COA of working standard • Firm submitted that Dissolution criteria Q=80% in 30 minutes according to FDA guidelines, in our document it was a typographical error and submitted updated SOP for analysis and revised specifications. ***However, FDA review documents of innovator product specifies that dissolution criteria shall be NLT Q in 15 min*** • Firm has submitted COA of Working Standards from Fuxin Long Rui Pharmaceutical Co., Ltd. • Firm has submitted readable copies of Chromatograms of assay at initial time point. ***However, COA at initial time point is not submitted*** • Firm has submitted Raw data sheet of accelerated stability study at 3rd month time point • The firm has submitted updated SOP for analysis containing same lambda / wavelength as mentioned on chromatograms • Firm has submitted a certificate of HPLC software 21CFR compliance. ***However, audit trail reports on product testing for complete stability studies is not submitted*** • Record of Digital data logger for temperature & humidity monitoring of stability chambers at accelerated conditions is submitted • Firm has submitted Fee Rs. 7,500/- on deposit slip No. 1105707479 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
Decision: Approved with innovator's specifications. • **Registration letter shall be issued after submission of revised dissolution specifications of *NLT Q in 15 min* of applied product as per innovator's product** • **Submission of batch analysis certificate of initial time point of all stability batches, as per submitted analytical record.** • **Submission of audit trail reports on product testing for complete stability studies** • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

b. Deferred cases of form 5 for consideration of turn:

29.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Aprowim 150mg Tablet Apromit 150mg Tablet
	Composition	Each film coated tablet contains: Irbesartan ……. 150mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12135 dated 06-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's, 1x28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ABISART 150 irbesartan 150mg film coated tablet TGA approved.
	Me-too-status	Irbisaff Tablet 150mg by M/s Saffron Pharmaceuticals (Reg#77189)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Previous Remark of the Evaluator [XI]	
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	
30.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Aprowim 300mg Tablet Apromit 300mg Tablet
	Composition	Each film coated tablet contains:

		Irbesartan …. ……..300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12134 dated 06-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's, 1x28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ABISART 300 irbesartan 300mg film coated tablet TGA approved.
	Me-too-status	Irbisaff Tablet 300mg by M/s Saffron Pharma (Reg#77188)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Previous Remark of the Evaluator [XI]	
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	
31.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Oseltawir 75mg Capsule Infu-Wim 75mg Capsule
	Composition	Each Capsule contains: Oseltamivir phosphate equivalent to oseltamivir …. 75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12120 dated 06-03-2019 Rs.20,000 06-03-2019
	Pharmacological Group	Neuraminidase Inhibitor
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TAMIFLU (30mg, 45mg, 75mg) capsules (USFDA approved).
	Me-too-status	Ostavir-Flu 75mg Capsule by Zafa Pharmaceutical (Reg#42333)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Previous Remark of the Evaluator [XI]	
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	
32.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Lorwim 25mg Tablet Lormit 25mg Tablet
	Composition	Each film coated tablet contains: Losartan Potassium ……..…. 25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12119 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cozaar 25mg film-coated tablets. MHRA approved
	Me-too-status	Lotass 25mg Tablet by M/s Getz Pharma (Reg# 66802)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Previous Remark of the Evaluator [XI]	
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	
33.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Lorwim 50mg Tablet Lormit 50mg Tablet
	Composition	Each film coated Tablet contains:

		Losartan Potassium …. 50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12121 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cozaar 50 mg film-coated tablets. MHRA approved
	Me-too-status	Lotass 50mg Tablet by M/s Getz Pharma (Reg# 66803)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Previous Remark of the Evaluator [XI]	
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	
34.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	NISIM 100mg Tablet
	Composition	Each Tablet contains: Nimesulide …….. 100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12133 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	NSAIDS
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ALGIMESIL 100 mg tablets AIFA Italy Approved
	Me-too-status	Nimcid Tablets by Unexolabs (Reg#46336)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Previous Remark of the Evaluator [XI]	The firm revised master formulation and manufacturing outline and removed coating composition and coating procedure.
	Previous Decision (296-DRB)	**Deferred for consideration on its turn**
	Evaluation by PEC	
	Decision: Approved with innovator's specifications. Keeping in view the approval status of Nimesulide 100mg tablet in EMA, Registration Board approved the applied formulation of Nimesulide Tablets 100mg with a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice. • **Treatment of acute pain** • **Primary dysmenorrhea** **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
35.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Passit 10mEq tablet Citro-P 10mEq tablet
	Composition	Each Extended release tablet contains: Potassium Citrate …. 10mEq (1080mg)
	Dairy No. date of R &I fee	Form-5 Dy.No 12122 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Urinary Alkalinizing agent
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Urocit-K Extended-release tablets USFDA Approved
	Me-too-status	Exocite XR 10mEq tablets by M/s Vision Pharmaceuticals (Reg#080827)

	GMP Status	GMP Certificate issued on 10-12-2018.
	Previous Remark of the Evaluator [XI]	• The firm has claimed manufacturer's specifications but the official monograph is available in USP. • The firm submitted undertaking at the end of form 5 duly signed by the technical persons. • The firm submitted complete master formulation and manufacturing method for the applied product.
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved with USP specifications. **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
36.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Thiowim Injection 4mg/2ml
	Composition	Each 2ml ampoule contains: Thiocolchicoside …… 4mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12126 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of form	Form-5
	Finished product specifications	
	Pack size and Demand Price	6ampx2ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	THIOCOLCHICOSIDE PHARMY II 4 mg/2 ml, solution for injection ampule. ANSM approved
	Me-too-status	Thiocol 4mg / 2ml Injection by M/s Ray Pharma (Reg#66712)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Previous Remark of the Evaluator [XI]	• Firm informed the use of type I glass container as primary packaging material of applied formulation • The firm has applied for USP specifications and the product is not present in available pharmacopoeias.
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved with innovator's specifications **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

37.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Icare 40mg dry powder Injection
	Composition	Each vial contains: Omeprazole (as Sodium) ……..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 15039 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial (TGA Approved)
	Me-too-status	Prisma 40mg IV Injection by M/s Rasco Pharma (Reg#82762)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as

		of today. However the points of improvements have been discussed and agreed by the representatives of the firm. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Previous Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	• Registration Board in its 291st meeting held on 02-04th September 2019 allowed contract manufacturing from M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for the following sections: i. Dry powder Injectable (Penicillin) ii. Liquid ampoule Injectable (General) iii. Dry powder Lyophilized Injectable (General) iv. Large Volume Vial Injectable (General)
	Decision: Approved with innovator's specifications • **Registration letter shall be issued upon submission of:** • **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years for both M/s Kanel Pharma and M/s English Pharmaceuticals Industries.** • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore**	
38.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Escare 40mg dry powder Injection
	Composition	Each vial contains: Esomeprazole (as Sodium)……40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 15038 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Esomeprazole 40mg Powder for Solution for Injection/Infusion MHRA Approved
	Me-too-status	Esobrain Injection 40mg by M/s WinBrains Research Laboratories, (Reg#85072)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was:

		Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Previous Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	• Registration Board in its 291st meeting held on 02-04th September 2019 allowed contract manufacturing from M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for the following sections: i. Dry powder Injectable (Penicillin) ii. Liquid ampoule Injectable (General) iii. Dry powder Lyophilized Injectable (General) iv. Large Volume Vial Injectable (General)
	Decision: Approved with innovator's specifications • **Registration letter shall be issued upon submission of:** • **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years for both M/s Kanel Pharma and M/s English Pharmaceuticals Industries.** • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore**	
39.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Kanprazole 40mg dry powder Injection
	Composition	Each vial contains: Pantoprazole (as Sodium sesquihydrate) ……40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 15040 dated 07-03-2019 Rs.50,000/- 07-3-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 40mg Powder for Solution for Injection MHRA Approved
	Me-too-status	Panpak 40mg IV Injection by M/s Rasco Pharma (Reg#82763)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was:

		Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm. Certificate of GMP Issued to English Pharmaceuticals on 16-1-2018.
	Previous Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation • The firm did not submitted revised master formulation adjusting the weight of API considering the hydrated form
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	• Registration Board in its 291st meeting held on 02-04th September 2019 allowed contract manufacturing from M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for the following sections: i. Dry powder Injectable (Penicillin) ii. Liquid ampoule Injectable (General) iii. Dry powder Lyophilized Injectable (General) iv. Large Volume Vial Injectable (General)
	Decision: Approved with innovator's specifications • **Registration letter shall be issued upon submission of:** • **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years for both M/s Kanel Pharma and M/s English Pharmaceuticals Industries.** • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore**	
40.	Name and address of manufacture / Applicant	M/s Sapient Pharma., 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Olmem 5mg/40mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……...5mg Olmesartan Medoxomil…….40mg
	Dairy No. date of R &I fee	Dy.No 12199 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Innovator's specification
	Pack size and Demand Price	20's, 28's, 30's, 56's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor (5mg /20mg, 10mg /20mg, 5mg /40mg, 10mg /40mg) film coated tablets of (USFDA Approved)
	Me-too-status	Olesta-AM 5mg /40mg of M/s Searle Pakistan (Reg#076188)

	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019
	Previous Remark of the Evaluator [XI]	Firm submitted all documents as required in enclosure of form 5.
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	
41.	Name and address of manufacture / Applicant	M/s Sapient Pharma., 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Olmem 5/20mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……..…5mg Olmesartan Medoxomil……..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12198 dated 06-03-2019 Rs.20,000/- 04-3-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Innovator's specification
	Pack size and Demand Price	20's, 28's, 30's, 56's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor (5mg /20mg, 10mg /20mg, 5mg /40mg, 10mg /40mg) film coated tablets of (USFDA Approved)
	Me-too-status	Olesta-AM 5/20mg of M/s Searle Pakistan (Reg#076187)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019.
	Previous Remark of the Evaluator [XI]	Firm submitted all documents as required in enclosure of form 5.
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	
42.	Name and address of manufacture / Applicant	M/s Sapient Pharma., 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Olmem 10/20mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……10mg Olmesartan Medoxomil……..…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12200 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Innovator's specification
	Pack size and Demand Price	20's, 28's, 30's, 56's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor (5mg /20mg, 10mg /20mg, 5mg /40mg, 10mg /40mg) film coated tablets of (USFDA Approved)
	Me-too-status	Olesta-AM 10/20mg by M/s Searle Pakistan (Reg#076189)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019
	Previous Remark of the Evaluator [XI]	Firm submitted all documents as required in enclosure of form 5.
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	
43.	Name and address of manufacture / Applicant	M/s Sapient Pharma., 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Smval 5/80mg Tablets
	Composition	Each Tablet Contains: Amlodipine besylate……..…5mg Valsartan……..…80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12195 dated 06-03-2019 Rs.20,000/- 04-3-2019

	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's, 2x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/80mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/80 of M/s Jupiter Pharma (Reg.#081931)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019
	Previous Remark of the Evaluator [XI]	• The firm revise the label claim from uncoated to film coated tablets along with submission of Rs. 5000/- on deposite slip No. 0766456 date 02-09-2020. The firm also corrected the salt form of amlodipine in label claim as per reference formulation without considering the salt factor. The revised label claim is as under: Each film coated Tablet Contains: Amlodipine (as besylate) ……..…5mg Valsartan……..…80mg • Firm submitted all documents as required in enclosure of form 5.
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved with following label claim: **Each film coated Tablet Contains:** **Amlodipine (as besylate) ……..…5mg** **Valsartan……..…80mg** **Firm shall submit the differential fee of Rs. 25,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance) and correction/change of formulation from un-coated tablet to film coated tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**	
44.	Name and address of manufacture / Applicant	M/s Sapient Pharma., 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Smval 5/160mg Tablets
	Composition	Each Tablet Contains: Amlodipine besylate……5mg Valsartan…….160mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12196 dated 06-03-2019 Rs.20,000/- 4-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's, 2x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/160mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/160 of M/s Jupiter Pharma (Reg.#081932)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019
	Previous Remark of the Evaluator [XI]	• The firm revise the label claim from uncoated to film coated tablets along with submission of Rs. 5000/- on deposite slip No. 0766489 date 02-09-2020. The firm also corrected the salt form of amlodipine in label claim as per reference formulation without considering the salt factor. The revised label claim is as under: Each film coated Tablet Contains: Amlodipine (as besylate) ……5mg Valsartan……..…160mg

		• Firm submitted all documents as required in enclosure of form 5.
	Previous Decision (296-DRB)	• **Deferred for consideration on its turn.**
	Evaluation by PEC	•
	Decision: Approved with following label claim: **Each film coated Tablet Contains:** **Amlodipine (as besylate) ……..…5mg** **Valsartan……..…160mg** **Firm shall submit the differential fee of Rs. 25,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance) and correction/change of formulation from un-coated tablet to film coated tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**	
45.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar. ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefial Capsule 400mg
	Composition	Each Capsule Contains: Cefixime monohydrate eq to Cefixime…….…400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 14937 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX capsules 400mg, (USFDA approved)
	Me-too-status	Xalfocin 400mg Capsule by Martin Dow Karachi (Reg. 80646)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Previous Remark of the Evaluator XI	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • Fee of Rs. 50,000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	

	Decision: Approved with Specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022. • **Applicant shall submit the full fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, since initially fee was submitted bythe contract manufacturer instead of the applicant.** • **Submission of GMP audit report for both M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals from QA&LT Division, valid within last three years** • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**	
46.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefial 100mg/5ml Dry Suspension
	Composition	Each 5ml contains: Cefixime Trihydrate eq to Cefixime……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 14940 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	30ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefixime 100mg/5ml Powder for Oral Suspension MHRA Approved
	Me-too-status	Fix 100mg/5ml Suspension by M/s Aptcure (Pvt) Ltd (Reg. 85229)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Previous Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • Fee of Rs. 50000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved.	

	• **Applicant shall submit the full fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, since initially fee was submitted bythe contract manufacturer instead of the applicant.** • **Submission of GMP audit report for both M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals from QA&LT Division, valid within last three years** • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**	
47.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefixon 1g Injection IV
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…….1g
	Dairy No. date of R &I fee	Form-5 Dy.No 14939 dated 07-03-2019 Rs.50,000/- 7-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin 1g Powder for solution for injection or infusion MHRA Approved
	Me-too-status	Ceftro Injection 1gm IV by Biocef (Pvt) Ltd, (Reg. No. 82740)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Previous Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • Firm submitted duly filled form 5 signed by the signatory and undertaking at the end of form 5 signed by technical persons • Fee of Rs. 50,000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. However, the deposit slip contains both the name of M/s Aulton Pharmaceutical and its DML No. 000828. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing • The firm did not mentioned type of primary packaging material of applied formulation whether it is type I, II or III glass container.

	Previous Decision (296-DRB)	**Deferred for consideration on its turn**
	Evaluation by PEC	
	Decision: Approved. • **Registration letter shall be issued after mentioning the type of primary packaging material of applied formulation** • **Applicant shall submit the full fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, since initially fee was submitted bythe contract manufacturer instead of the applicant.** • **Submission of GMP audit report for both M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals from QA&LT Division, valid within last three years** • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**	
48.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefixon 500mg injection IV
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 14936 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 500mg powder for solution for injection MHRA Approved
	Me-too-status	Ceftro Injection 500mg IV by Biocef (Pvt) Ltd, (Reg. No. 82738)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Previous Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • Firm submitted duly filled form 5 signed by the signatory and undertaking at the end of form 5 signed by technical persons • Fee of Rs. 50000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. However the deposit slip contain both the name of M/s Aulton Pharmaceutical and its DML No. 000828. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals

		• The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing • The firm did not mentioned type of primary packaging material of applied formulation whether it is type I, II or III glass container
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved. • **Registration letter shall be issued after mentioning the type of primary packaging material of applied formulation** • **Applicant shall submit the full fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, since initially fee was submitted bythe contract manufacturer instead of the applicant.** • **Submission of GMP audit report for both M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals from QA&LT Division, valid within last three years** • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**	
49.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefixon 250mg injection IV
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 14938 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin 250mg Powder for solution for injection MHRA Approved
	Me-too-status	Ceftro Injection 250mg IV by Biocef (Reg. No. 82737)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Previous Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • The firm submitted duly filled form 5 signed by the signatory and undertaking at the end of form 5 signed by the technical persons • Fee of Rs. 50,000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. However the deposit slip

		contain both the name of M/s Aulton Pharmaceutical and its DML No. 000828. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing • The firm did not mentioned type of primary packaging material of applied formulation whether it is type I, II or III glass container • The firm did not submit master formulation for the applied product.
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	
	Decision: Approved. • **Registration letter shall be issued after mentioning the type of primary packaging material of applied formulation and submission of master formulation** • **Applicant shall submit the full fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, since initially fee was submitted bythe contract manufacturer instead of the applicant.** • **Submission of GMP audit report for both M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals from QA&LT Division, valid within last three years** • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**	
50.	Name and address of manufacture / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Pipetazo 4.5g Injection
	Composition	Each Vial Contains: Piperacillin (as Sodium)……..4g Tazobactam (as Sodium)……..0.5g
	Dairy No. date of R &I fee	Form-5 Dy.No 17419 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Penicillin and beta-lactamase inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN (piperacillin and tazobactam, 4gm/0.5gm) for injection, for intravenous use. **USFDA** approved
	Me-too-status	Tacip 4.5gm Injection by M/s Macter Int. (Reg#73632)
	GMP Status	M/s Rotex Pharma Islamabad was inspected on 19-09-2018 and recommendations of inspection was: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm did not possess required machinery and equipments for said purpose. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Previous Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Rotex Pharma Pvt Ltd. along with undertaking at the end of form 5.

		• A copy of contract manufacturing agreement between M/s Rotex Pharma Pvt Ltd and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 29 approved sections of applicant. i.e. M/s Rotex Pharma Pvt Ltd. • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 04 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	• Registration Board in its 291st meeting held on 02-04th September 2019 allowed contract manufacturing from M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for the following sections: i. Dry powder Injectable (Penicillin) ii. Liquid ampoule Injectable (General) iii. Dry powder Lyophilized Injectable (General) iv. Large Volume Vial Injectable (General)
	Decision: Approved. **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years for both M/s Rotex Pharma and M/s English Pharmaceuticals Industries.**	
51.	Name and address of manufacture / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Pipetazo 2.25g Injection
	Composition	Each Vial Contains: Piperacillin (as Sodium)…..……..2g Tazobactam (as Sodium)……0.25g
	Dairy No. date of R &I fee	Form-5 Dy.No 17416 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Penicillin and beta-lactamase inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN (piperacillin and tazobactam, 2gm/0.25gm) for injection, for intravenous use. **USFDA** approved
	Me-too-status	Tanzo Injection by M/s Bosch Pharmaceutical (Reg. No. 39593)
	GMP Status	M/s Rotex Pharma Islamabad was inspected on 19-09-2018 and recommendations of inspection was: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm did not possess required machinery and equipments for said purpose. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Previous Remark of the Evaluator XI	• Form 5 submitted by the applicant i.e. M/s Rotex Pharma Pvt Ltd. along with undertaking at the end of form 5. • A copy of contract manufacturing agreement between M/s Rotex Pharma Pvt Ltd and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 29 approved sections of applicant. i.e. M/s Rotex Pharma Pvt Ltd.

		• The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 04 applied products for contract manufacturing • The firm mentioned the use of type I glass container as primary packaging material of applied formulation
	Previous Decision (296-DRB)	**Deferred for consideration on its turn.**
	Evaluation by PEC	• Registration Board in its 291st meeting held on 02-04th September 2019 allowed contract manufacturing from M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for the following sections: i. Dry powder Injectable (Penicillin) ii. Liquid ampoule Injectable (General) iii. Dry powder Lyophilized Injectable (General) iv. Large Volume Vial Injectable (General)
	Decision: Approved. **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years for both M/s Rotex Pharma and M/s English Pharmaceuticals Industries.**	

c. Deferred cases of Human Drugs on Form 5:

52.	Name and address of manufacture / Applicant	M/s Gulf Pharmaceuticals Plot # 49 street-5 National Industrial zone Rawat Islamabad,
	Brand Name + Dosage Form and Strength	Gulped 25mg Tablet
	Composition	Each film coated tablet contains: Levosulpiride…….25 mg
	Dairy No. date of R &I fee	Dy.No.2684; 24-02-2017; Rs.20,000/- (24-02-2017)
	Pharmacological Group	Antidepressant
	Type of form	Form 5
	Finished product specifications	Manufacturer specification
	Pack size and Demand Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Italian Medicine Agency
	Me-too-status	Scipride 25mg tablet by M/s Getz Pharma (Reg#057902)
	GMP Status	Last GMP inspection conducted on 18-05-2016, and the report concludes that firm is complying GMP.
	Previous Remark of the Evaluator	•
	Previous Decision (278-DRB)	• Deferred for clarification of formulation since reference product is available as uncoated tablet whereas firm has applied for film coated formulation.
	Evaluation by PEC	• The firm has submitted revised form 5 and master formulation and revised the formulation from film coated to uncoated tablets along with submission of Rs 7500/- on deposit slip# 961250993063. The revised label claim is as under: Each uncoated tablet contains: Levosulpiride…….25 mg
	Decision: Approved with innovator's specifications and following label claim: **Each uncoated tablet contains:** **Levosulpiride…….25 mg**	
53.	Name and address of manufacture / Applicant	M/s Gulf Pharmaceuticals Plot # 49 street-5 National Industrial zone Rawat Islamabad,
	Brand Name + Dosage Form and Strength	Gulped 50mg Tablet
	Composition	Each film coated tablet contains: Levosulpiride…….50 mg
	Dairy No. date of R &I fee	Dy.No.2689; 24-02-2017; Rs.20,000/- (24-02-2017)
	Pharmacological Group	Antidepressant
	Type of form	Form 5
	Finished product specifications	Manufacturer specification

	Pack size and Demand Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Italian Medicine Agency
	Me-too-status	Scipride 50mg tablet by M/s Getz Pharma (Reg#057903)
	GMP Status	Last GMP inspection conducted on 18-05-2016, and the report concludes that firm is complying GMP.
	Previous Remark of the Evaluator	•
	Previous Decision (278-DRB)	• Deferred for clarification of formulation since reference product is available as uncoated tablet whereas firm has applied for film coated formulation.
	Evaluation by PEC	• The firm has submitted revised form 5 and master formulation and revised the formulation from film coated to uncoated tablets along with submission of Rs 7500/- on deposit slip# 727236260767. The revised label claim is as under: Each uncoated tablet contains: Levosulpiride…….50 mg
	Decision: Approved with innovator's specifications and following label claim: **Each uncoated tablet contains:** **Levosulpiride…….50 mg**	
54.	Name and address of manufacture / Applicant	"M/s Inventor Pharma., Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Lincoventor 300mg/ml
	Composition	Each 1ml ampoule contains: Lincomycin as HCl.…300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 74 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Lincosamides
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	LINCOMYCIN LWS lincomycin (as hydrochloride monohydrate) 300 mg/1 mL solution for injection ampoule; TGA Australia Approved
	Me-too-status	LincoShar Injection of M/s Sharex Labs (Reg. # 065681)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Previous Remark of Evaluator [XI]	• Letter of deficiencies sent on 21-04-2020 and reminder on 04-11-2020 but no reply received yet • You have not mentioned label claim in form 5. Please mention the label claim • Revise weight of API in master formulation considering the salt factor. Moreover mention the hydrated form of API in label claim and master formulation • You have not performed terminal sterilization, justify • Mention type of primary packaging material of applied formulation whether it is type I, II or III
	Previous Decision (297-DRB)	Deferred for following: • You have not mentioned label claim in form 5. Please mention the label claim • Revise weight of API in master formulation considering the salt factor. Moreover, mention the hydrated form of API in label claim and master formulation • not performed terminal sterilization • Mention type of primary packaging material of applied formulation whether it is type I, II or III

	Evaluation by PEC	• The firm mentioned the label claim without submission of applicable fee. The submitted label claim is as under: Each ml contains: Lincomycin HCl monohydrate eq. to Lincomycin ..…300mg • The firm submitted that product is sterilized by membrane filtration using 0.2micron membrane filter and filled aseptically. Hence no need for terminal sterilization • The firm submitted glass ampoule Type I as primary packaging material of applied formulation • The firm did not submit revised master formulation and did not revise weight of API in master formulation considering the salt factor and hydrated form.
	Previous Decision (307-DRB)	Deferred for following: • Submission of master formulation and revise weight of API considering the salt factor and hydrated form. • Scientific justification for not performing terminal sterilization
	Evaluation by PEC	• The firm have submitted revised master formulation and adjusted the weight of API considering the salt factor without submission of applicable fee. • The firm have submitted revised manufacturing outline and mentioned terminal sterilization process in manufacturing outline
	Decision: Approved with following label claim: Each ml contains: Lincomycin HCl monohydrate eq. to Lincomycin ..…300mg Firm shall submit the fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of hydrated form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
55.	Name and address of manufacture / Applicant	"M/s Inventor Pharma., Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Lincoventor 600mg/2ml
	Composition	Each 2ml contains: Lincomycin as HCl..…600mg
	Dairy No. date of R &I fee	Form-5 Dy.No 75 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Lincosamides
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	2ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	LINCOMYCIN LWS lincomycin (as hydrochloride monohydrate) 600 mg/2 mL solution for injection ampoule TGA approved
	Me-too-status	Olinc 600mg/2ml vial of M/s Bosch (Reg#025416)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Previous Remark of Evaluator [XI]	• Letter of deficiencies sent on 21-04-2020 and reminder on 04-11-2020 but no reply received yet • You have not mentioned label claim in form 5. Please mention the label claim • Revise weight of API in master formulation considering the salt factor. Moreover mention the hydrated form of API in label claim and master formulation • You have not performed terminal sterilization, justify • Mention type of primary packaging material of applied formulation whether it is type I, II or III
	Previous Decision (297-DRB)	Deferred for following: • You have not mentioned label claim in form 5. Please mention the label claim

		• Revise weight of API in master formulation considering the salt factor. Moreover mention the hydrated form of API in label claim and master formulation • You have not performed terminal sterilization, justify • Mention type of primary packaging material of applied formulation whether it is type I, II or III
	Evaluation by PEC	• The firm mentioned the label claim without submission of applicable fee. The submitted label claim is as under: Each 2ml contains: Lincomycin HCl monohydrate eq. to Lincomycin ..…600mg • The firm submitted that product is sterilized by membrane filtration using 0.2micron membrane filter and filled aseptically. Hence no need for terminal sterilization • The firm submitted glass ampoule Type I as primary packaging material of applied formulation • The firm submitted revised master formulation and revised weight of API in master formulation considering the salt factor and hydrated form.
	Previous Decision (307-DRB)	• Deferred for scientific justification for not performing terminal sterilization
	Evaluation by PEC	• The firm have submitted revised manufacturing outline and mentioned terminal sterilization process in manufacturing outline
	Decision: Approved with following label claim: Each 2ml contains: Lincomycin HCl monohydrate eq. to Lincomycin ..…600mg Firm shall submit the fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of hydrated form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
56.	Name and address of manufacture / Applicant	"M/s Inventor Pharma., Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Dicloin Injection 75mg/3ml
	Composition	Each 3ml ampoule contains: Diclofenac sodium…..75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 69 dated 01-01-2019 Rs.20,000/- 31-12-2018
	Pharmacological Group	NSAIDS
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	3ml (1x5's); As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac Sodium 75 mg/3 ml Solution for Injection MHRA Approved
	Me-too-status	V- Ren Liquid Injection of M/s Regal Pharmaceuticals (Reg#082002)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Previous Remark of Evaluator [XI]	• Letter of deficiencies sent on 21-04-2020 and reminder on 04-11-2020 but no reply received yet • Revise weight of API in master formulation not considering the salt factor • You have not performed terminal sterilization, justify • Mention type of primary packaging material of applied formulation whether it is type I, II or III • The manufacturer have claimed BP specifications while official monograph is not available in any pharmacopeia (USP, BP, IP, JP).
	Previous Decision (297-DRB)	Deferred for following:

		• Revise weight of API in master formulation not considering the salt factor • You have not performed terminal sterilization, justify • Mention type of primary packaging material of applied formulation whether it is type I, II or III
	Evaluation by PEC	• The firm submitted revised master formulation and revised the weight of API without considering the salt factor. However, firm have mentioned the 10% excess addition of API • The firm submitted that product is sterilized by membrane filtration using 0.2micron membrane filter and filled aseptically. Hence no need for terminal sterilization • The firm submitted glass ampoule (Ph.Eur. Type I) as primary packaging material of applied formulation
	Previous Decision (307-DRB)	Deferred for following: • Scientific justification for addition of 10% overage of API • Scientific justification for not performing terminal sterilization
	Evaluation by PEC	• The firm have submitted revised master formulation and removed the addition of 10% overage • The firm submitted that A known impurity is formed in the production of a parenteral dosage from of diclofenac sodium if terminally sterilized by autoclave. This impurity has been detected as 1-(2,6-dichlorophenyl) indolin-2qione, which is also an intermediate from which diclofenac sodium is generally synthesized. It is only the condition of the autoclave method (i.e., 123±2 degree C) that enforces the intramolecular cyclic reaction of diclofenac sodium forming indoline derivative and sodium hydroxide. The formation of this impurity has been found to depend on the initial pH of the formulation. The other excipients in the formulation do not have a role in this reaction. The concentration of the impurity in the resultant product in the ampule goes beyond the limit of the raw materials in the pharmacopoeias. It is thus preferable to use an alternative sterilization method, that is, an aseptic filtration method in which the formation of the impurity can be avoided. Hence, the Aseptic filtration method is adopted.
	Decision: Approved with innovator's specifications. Firm shall submit the differential fee of Rs. 7,500/- for correction/pre-approval change in master formulation and product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	

Registration applications of Human Drugs on Form 5F (Import)

57.	Name, address of Applicant / Importer	Atco Pharma International (Pvt.) Ltd, B-18, S.I.T.E, Karachi.
	Details of Drug Sale License of importer	**License No: 1184** **Address:** B-18, S.I.T.E., Karachi **Address of Godown:** B-4, S.I.T.E., Karachi **Validity:** 23-1-2022. **Status:** License to sell, stock and exhibit for sale, distribute and sell drugs by way of whole sale.
	Name and address of marketing authorization holder (abroad)	Ferring Arzneimittel GmbH Fabrikstrasse 7 24103 Kiel Germany
	Name, address of manufacturer(s)	Manufacturer and primary packaging site: Ferring GmbH Wittland 11 24109 Kiel Germany Secondary packaging site: Ferring International Centre S.A. Chemin de la Vergognausaz 50, Ch-1162 St. Prex, Switzerland or Ferring-Leciva, a.s. Ke Skále 455 Vestec u Prahy, 25242 Czech Republic

	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. Ag1525) dated 19-11-2019 ***issued by State Social Services Agency Schleswig-Holstein Health and Consumer Protection Adolf-Westphal-Str. 4 24143 Kiel Germany*** for PABAL® RTS 100 micrograms /ml solution for injection. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspections. The name of importing country on CoPP is mentioned as the Islamic Republic of Pakistan.
	Details of letter of authorization / sole agency agreement	Firm has submitted colored copy of product specific Power of Attorney from Ferring GmbH/ Wittland 11, 24109 Kiel, Germany in the name of Atco Pharma International (Pvt.) Ltd B-18, S.I.T.S., Manghopir Road, Karachi 75700 Pakistan which is valid upto 31-12-2021.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 22749, Date of submission: 20-08-2021
	Details of fee submitted	PKR 100,000/- dated 28-01-2021 Deposit Slip No:2050341
	The proposed proprietary name / brand name	PABAL® RTS 100 micrograms /ml solution for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Carbetocin 100 micrograms/ml.
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	Antihemorrhagic
	Reference to Finished product specifications	In house Specification
	Proposed Pack size	5 x 1ml vial.
	Proposed unit price	Rs. 150,000/- pack of 5 vials.
	The status in reference regulatory authorities	PABAL® RTS 100 micrograms /ml solution for injection by M/s Ferring Medicinal products GmbH/Germany
	For generic drugs (me-too status)	Not Applicable
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Polypeptide Laboratories 7 rue de Boulogne, Technopole du Rhin. Strasbourg 67100 France.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls of material, control of critical steps and intermediates, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Seven batches have been placed on stability at long term (-20ºC ± 5ºC) and accelerated conditions (25ºC ± 2ºC / 60% RH ± 5% RH). The study is scheduled to run for 48 months for the seven Batches. So far, 48 months data is available for five batches and 36 months data is available for two batches. (Batches: MZ77098, MZ77103, MZ77133, MZ77135, MZ77140, MZ77156, MZ77157)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturers, manufacturing process and control of critical steps validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Applicable since the applied product is innovator drug products
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	USP Type 1 colourless glass vial (2R) sealed with a bromobutyl rubber stopper (type I according to Ph. Eur.) and an aluminium crimp cap with tear-off over cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The long-term storage condition at 30ºC/ 75% RH for 36 months and at accelerated storage conditions at 40ºC/75% RH for 6 months. Shelf life: 3 years.

Batch No.	Mfg. Date	Initiation date
H14020	13 Aug 2013	08 Oct 2013
H14025	27 Aug 2013	15 Oct 2013
H14830	03 Sep 2013	15 Oct 2013

Remarks of Evaluator [XI]:

Section	Observations	Response

1.3.4	Submit Valid copy of Drug Sale License,	Firm has submitted drug sale License; details are given; **License No: 054** **Address:** B-18, S.I.T.E., Karachi **Address of Godown:** B-4, S.I.T.E., Karachi **Validity:** 22-1-2024. **Status:** License to sell, stock and exhibit for sale, distribute and sell drugs by way of whole sale.
	• Submit valid original legalized product specific sole agency agreement (valid upto 31-12-2021.)	The firm submitted that it is under process
1.5.2.	• Describe Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit as per guidance document	Reply not submitted
1.6.5	• Submit valid GMP certificate of drug substance manufacturer as the submitted GMP is expired.	Firm has submitted GMP certificate No. 20MPP075HFR01 of M/s Polypeptide Laboratories France 7 rue de Boulogne, Technopole du Rhin. Strasbourg 67100 France issued based on inspection conducted on 10-12-2020, valid upto three years from date of issue
3.2.S.2	• Copy of quality agreement shall be included as manufacturing, processing, packaging or testing is performed by an outside contractor or third party contractor.	Reply not submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.	Reply not submitted
3.2.P.1.2	• In composition of drug product, you have mentioned "Each vial is filled with 1.28 g solution for injection to ensure an extractable volume of 1.0 mL". clarification is required for declaring filled volume in units of grams	During production of Pabal RTS at Ferring GmbH in Kiel, a gravimetric in process control (IPC) test for fill mass. For this test, the extractable volume is transferred to scale and measured in gram. As the density of solution is very consistent (within a range of 1.01 to 1.02 g/ml), the gravimetric IPC test with the given limits of 1.23 g – 1.33 g ensures the required extractable volume of 1.0 ml of finished product is kept
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided without referring to other section of form 5F	COA of primary / secondary reference standard is not provided

Decision: Registration Board while considering the non-availability of applied formulation in Pakistan and its indicated use, approved the product with innovator's specifications with condition of submission of following before issuance of registration letter:

- **Valid original legalized product specific letter of authorization / sole agency agreement**
- **Copy of quality agreement as manufacturing, processing, packaging or testing is performed by an outside contractor or third party contractor;**
- **Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer**
- **COA of primary / secondary reference standard including source and lot number without referring to other section of form 5F**
- **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

58.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals(Pvt.) Ltd Lahore**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals(Pvt.) Ltd., 28km Ferozepur Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26031 Dated 20/09/2021
	Details of fee submitted	PKR 30,000/-: dated 14/09/2021
	The proposed proprietary name / brand name	Agomet 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Agomeltaine…… 25mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Melatonin agonist (i.e., MT1 and MT2 receptor-site agonism) and a 5HT2c antagonist.
	Reference to Finished product specifications	In-House
	Proposed Pack size	10's, 14's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Valdoxan Tablet 25mg, Company: Servier Laboratories Limited
	For generic drugs (me-too status)	Agoviz by Pharmevo Reg No: 086887
	GMP status of the Finished product manufacturer	License granted on 08/04/2006 and renewed on 08/04/2021 General tablet section approved and GMP certificate on 31/08/2021.
	Name and address of API manufacturer.	Name: Shanku's Pharmaceuticals Address: Plot No 9, 10, 11 Milan Industrial Estate, Santej, Ta: Kalol, Dist: Gandhinagar – 382721, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical

		form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches :(AGO/07-15/012, AGO/07-15/013 & AGO/07-15/014)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Agoviz 25mg tablet by performing quality tests (Identification, Assay, and Dissolution). CDP was applicable and has been submitted.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, robustness and Limit of Quantification.

STABILITY STUDY DATA			
Manufacturer of API	Name: Shanku's Pharmaceuticals Address: Plot No 9, 10, 11 Milan Industrial Estate, Santej, Ta: Kalol, Dist: Gandhinagar – 382721, Gujrat, India.		
API Lot No.	AGM2.t004		
Description of Pack (Container closure system)	Alu-Alu blisters, each containing Yellow color, round biconvex film coated tablets, having breaking line on upper side & lower side is plain. One side of blister is printed with labeling specification. After primary packing blister is packed in specific hard card unit carton along with Patient information leaflet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR21-046/T2/S1	RD/PR21-046/T2/S2	RD/PR21-046/T2/S3
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted copy of Last inspection Report conducted on 24/01/2018 (Daclatasvir), 06/03/2017 (Sofosbuvir)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Food and drug control administration Gandhinagar,Gujarat State to Shanku's Pharmaceuticals India valid till 24/08/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.12259/2020/DRAP-AD-G(I&E) dated 31/08/2020 is submitted wherein the permission to import API Agomelatin for the purpose of test/analysis and stability studies is granted. AD Attested invoice E-053/2020-22 Dated.18/11/2020 is also submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2. S.7	Title of long-term stability sheets mentioned that the storage condition was 30°C ±2°C /RH 65%±5%RH, while the conclusion of all three stability batches specified that drug substance was kept at 30°C ±2°C /RH 60%±5%RH, clarification is required in this regard.	Firm replied that, upon query, it is informed by API Manufacturer that there is a typo error in conclusion of stability batches while the conditions for stability testing were 30°C ±2°C/RH65%±5% RH. Firm submitted the revised stability data sheet of all three batches of drug substance.

Decision: Approved with Innovator's specifications.

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

59.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No.30262 dated 05/11/2021
	Details of fee submitted	PKR 30,000/-: dated: 06/10/2021
	The proposed proprietary name / brand name	Ketor Tablets 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ketorolac Tromethamine……10mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10's, 20's, 30's & 40's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Toradol Tablets 10mgFDA
	For generic drugs (me-too status)	Yukon Tablet 10mg CCL Pharma
	GMP status of the Finished product manufacturer	license granted on 28/10/2019 Tablets (General & Psychotropic)
	Name and address of API manufacturer.	SYMED LABS LIMITED 8-2-293/174/3, Beside BN Reddy Colony, Road No. 14, Banjara Hills, Hyderabad, Telangana-500 034 INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ketorolac Tromethamine is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (KITE M001, KITE M002 & KITE M003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Toradol 10mg Tablet Jar Roche Laboratories by performing quality tests (Appearance, Identification, Disintegration time, Assay & Dissolution). CDP Is performed with medium 0.1NHCl, Acetate Buffer 4.5 & Buffer 6.8
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	SYMED LABS LIMITED 8-2-293/174/3, Beside BN Reddy Colony, Road No. 14, Banjara Hills, Hyderabad, Telangana-500 034 INDIA.		
API Lot No.	6KTL0010120		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 3 & 6 (Months) Real Time: 3 & 6 (Months)		
Batch No.	20SB-104-01	20SB-104-01	20SB-104-01
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	08-02-2021	08-02-2021	08-02-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate L. Dis. No. 8091/E1/2018 issued by Drugs Control Administration valid till 27/05/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase invoice No.EXP/1391 – DRAP-AD dated 06/03/2020 is submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks OF Evaluator:		

S.No.	Deficiencies/ Short-comings	Response of the Firm
1.	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted that Lot no.6KTL0070119 has been used in the manufacturing of trial batches ,DRAP attested invoice of same batch has also been submitted.

Decision: Approved with USP specifications.

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

60.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32360 dated 26/11/2021
	Details of fee submitted	PKR 30,000/-: dated 26/11/2021
	The proposed proprietary name / brand name	Olaxetine 3mg + 25mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Olanzapine USP….3mg Fluoxetine Hydrochloride USP equivalent to Fluoxetine……25mg
	Pharmaceutical form of applied drug	Hard gelatin capsule with blue opaque cap and yellow opaque body containing yellow powder.
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s, 14’s, 20’s & 30’s
	Proposed unit price	Rs. 280/- (10’s) Rs. 390/- (14’s) Rs. 530/- (20’s) Rs. 770/- (30’s)
	The status in reference regulatory authorities	SYMBYAX Capsules 3mg + 25mg by M/s Lilly USA, LLC, USA, USFDA Approved.
	For generic drugs (me-too status)	Co-Depricap Capsule 3mg + 25mg by M/s NABIQASIM Industries (Pvt.) Ltd., Karachi. (Reg. No.: 076136)
	GMP status of the Finished product manufacturer	Last GMP Inspection dated 03-12-2021 concludes that M/s Getz Pharma Pvt. Ltd. is considered to be operating at an

		acceptable level of compliance of GMP requirements. Capsule (General) section approved.
	Name and address of API manufacturer.	Olanzapine: M/s CADILA PHARMACEUTICALS LIMITED. 3203, G.I.D.C Estate, Ankleshwar - 393 002, District Bharuch, INDIA, Fluoxetine HCl: M/S SATYADIVIS PHARMACEUTICAL PVT.LTD INDIA Survey No. 10, I.D.A, Khazipally, Gaddapotaram (V), Jinnaram (M) Sangareddy Dist.,502319 India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Olanzapine: Official monograph of Olanzapine is present in USP. Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Fluoxetine HCl: Official monograph of Fluoxetine HCl is present in USP. Firm has submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Olanzapine: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (18OLZ012, 180LZ013, 180LZ014) Fluoxetine HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (FLU/001/15, FLU/002/15, FLU/003/15)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Co-Depricap Capsule 3mg + 25mg by M/s NABIQASIM Industries (Pvt.) Ltd. by performing quality tests (Appearance, Average weight, Assay and Dissolution). CDP has been performed against the same brand that is Co-Depricap Capsule 3mg + 25mg by M/s NABIQASIM Industries (Pvt.) Ltd., in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The APIs are releasing more than 85% in 15min, therefore, f2 value calculation is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including, system suitability, specificity, linearity, accuracy, precision repeatability, Stability of solution and range.

STABILITY STUDY DATA

Manufacturer of API	Olanzapine: M/s CADILA PHARMACEUTICALS LIMITED. 3203, G.I.D.C Estate, Ankleshwar - 393 002, District Bharuch, INDIA, Fluoxetine HCl: M/S SATYADIVIS PHARMACEUTICAL PVT.LTD INDIA Survey No. 10, I.D.A, Khazipally, Gaddapotaram (V), Jinnaram (M) Sangareddy Dist.,502319 India		
API Lot No.	Olanzapine: 20OLZ003 Fluoxetine: 1030920		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	561DS01	561DS02	561DS03
Batch Size	3000 Capsules	3000 Capsules	3000 Capsules
Manufacturing Date	23-11-2020	23-11-2020	23-11-2020
Date of Initiation	07-12-2020	07-12-2020	07-12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product for Mirab (Mirabegron) Extended release Tablets 25mg & 50mg on 12th December, 2017. Further, the said panel inspection report was discussed in 277th Drug Registration Board meeting held on 27 – 29th December, 2017. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.

<table>
<tr><td></td><td></td><td>• Related manufacturing area, equipment, personnel and utilities are GMP compliant.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td><u>Olanzapine:</u>
Firm has submitted copy of Good Manufacturing Practices Certificate (GMP) issued by Food & Drugs Control administration (Gujrat State) India valid till 30-08-2024.

<u>Fluoxetine HCl:</u>
Firm has submitted copy of Good Manufacturing Practices Certificate (GMP) issued by Drugs Control Administration (Telangana State) India valid till 21-01-2023.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Olanzapine:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>20OLZ003</td><td>CPL/BD/SAM/ 005/20-21</td><td>0.400kg</td><td>20-10-2020</td></tr>
</table>
Fluoxetine:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>1030920</td><td>F067/FLU</td><td>02Kg</td><td>23-10-2020</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="3">Remarks OF Evaluator:
<table>
<tr><th>Sr.no.</th><th>Observations</th><th>Response of the Firm</th></tr>
<tr><td>1.</td><td>Provide analytical Method Verification studies including specificity, accuracy and repeatability of both drug substance, performed by the Drug Product manufacturer.</td><td>Firm submitted the analytical method verification studies performed by drug product manufacturer for both drug substance.</td></tr>
<tr><td>2.</td><td>Please specify the time point at which NLT 80% (Q)of the drug release should achieved since the time point has not been mentioned in the specification of drug product.</td><td>Firm submitted the updated specification with time point at which NLT 80%(Q) of the drug release should achieved i.e. NLT 80%(Q) in 30 minutes.</td></tr>
</table></td></tr>
<tr><td colspan="3">Decision: Approved with USP specifications.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.</td></tr>
</table>

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
61.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32361 dated 26/11/2021
	Details of fee submitted	PKR 30,000/-: dated 26/11/2021
	The proposed proprietary name / brand name	Olaxetine 6mg + 25mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Olanzapine USP….6mg Fluoxetine Hydrochloride USP equivalent to Fluoxetine……25mg
	Pharmaceutical form of applied drug	Hard gelatin capsule with blue opaque cap and yellow opaque body containing yellow powder.
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	USP specs.
	Proposed Pack size	10’s, 14’s, 20’s & 30’s
	Proposed unit price	Rs. 470/- (10’s) Rs. 660/- (14’s) Rs. 900/- (20’s) Rs. 1290/- (30’s)
	The status in reference regulatory authorities	SYMBYAX Capsules 6mg + 25mg by M/s Lilly USA, LLC, USA, USFDA Approved.
	For generic drugs (me-too status)	Co-Depricap Capsule 6mg + 25mg by M/s NABIQASIM Industries (Pvt.) Ltd., Karachi. (Reg. No.: 076135)
	GMP status of the Finished product manufacturer	Last GMP Inspection dated 03-12-2021 concludes that M/s Getz Pharma Pvt. Ltd. is considered to be operating at an acceptable level of compliance of GMP requirements. Capsule (General) section approved.
	Name and address of API manufacturer.	<u>Olanzapine:</u> M/s CADILA PHARMACEUTICALS LIMITED. 3203, G.I.D.C Estate, Ankleshwar - 393 002, District Bharuch, INDIA, <u>Fluoxetine HCl:</u> M/S SATYADIVIS PHARMACEUTICAL PVT.LTD INDIA Survey No. 10, I.D.A, Khazipally, Gaddapotaram (V), Jinnaram (M) Sangareddy Dist.,502319 India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Olanzapine: Official monograph of Olanzapine is present in USP. Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Fluoxetine HCl: Official monograph of Fluoxetine HCl is present in USP. Firm has submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Olanzapine: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (18OLZ012, 180LZ013, 180LZ014) Fluoxetine HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (FLU/001/15, FLU/002/15, FLU/003/15)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against SYMBYAX Capsules 6mg + 25mg by M/s Lilly USA, LLC, USA, by performing quality tests (Appearance, Average weight, Assay and Dissolution). CDP has been performed against the same brand that is SYMBYAX Capsules 6mg + 25mg by M/s Lilly USA, LLC, USA, in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The APIs are releasing more than 85% in 15min, therefore, f2 value calculation is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including, system suitability, specificity, linearity, accuracy, precision repeatability, Stability of solution and range.

STABILITY STUDY DATA			
Manufacturer of API	Olanzapine: M/s CADILA PHARMACEUTICALS LIMITED. 3203, G.I.D.C Estate, Ankleshwar - 393 002, District Bharuch, INDIA, Fluoxetine HCl: M/S SATYADIVIS PHARMACEUTICAL PVT.LTD INDIA Survey No. 10, I.D.A, Khazipally, Gaddapotaram (V), Jinnaram (M) Sangareddy Dist.,502319 India		
API Lot No.	Olanzapine: 20OLZ003 Fluoxetine: 1030920		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	562DS01	562DS02	562DS03
Batch Size	3000 Capsules	3000 Capsules	3000 Capsules
Manufacturing Date	23-11-2020	23-11-2020	23-11-2020
Date of Initiation	07-12-2020	07-12-2020	07-12-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product for Mirab (Mirabegron) Extended release Tablets 25mg & 50mg on 12th December, 2017. Further, the said panel inspection report was discussed in 277th Drug Registration Board meeting held on 27 – 29th December, 2017. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	<u>Olanzapine:</u> Firm has submitted copy of Good Manufacturing Practices Certificate (GMP) issued by Food & Drugs Control administration (Gujrat State) India valid till 30-08-2024. <u>Fluoxetine:</u> Firm has submitted copy of Good Manufacturing Practices Certificate (GMP) issued by Drugs Control Administration (Telangana State) India valid till 21-01-2023.

<table>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Olanzapine:<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>20OLZ003</td><td>CPL/BD/SAM/ 005/20-21</td><td>0.400kg</td><td>20-10-2020</td></tr></table>
Fluoxetine:<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>1030920</td><td>F067/FLU</td><td>02Kg</td><td>23-10-2020</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="3">Remarks OF Evaluator:<table><tr><th>Sr.no.</th><th>Observations</th><th>Response of the Firm</th></tr><tr><td>1.</td><td>Provide analytical Method Verification studies including specificity, accuracy and repeatability of both drug substance, performed by the Drug Product manufacturer.</td><td>Firm submitted the analytical method verification studies performed by drug product manufacturer for both drug substance.</td></tr><tr><td>2.</td><td>Please specify the time point at which NLT 80% (Q)of the drug release should achieved since the time point has not been mentioned in the specification of drug product .</td><td>Firm submitted the updated specification with time point at which NLT 80%(Q) of the drug release should achieved i.e. NLT 80%(Q) in 30 minutes.</td></tr></table></td></tr>
<tr><td colspan="3">Decision: Approved with USP specifications.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.</td></tr>
<tr><td rowspan="3">62.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Bosch Pharmaceuticals (Pvt.) Ltd.,
Bosch House221, Sector 23, Korangi Industrial area, Karachi</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Bosch Pharmaceuticals (Pvt.) Ltd.,
Bosch House221, Sector 23, Korangi Industrial area, Karachi</td></tr>
<tr><td>Status of the applicant</td><td>☒ Manufacturer
☐ Importer
☐ Is involved in none of the above (contract giver)</td></tr>
</table>

	GMP status of the firm	Firm submitted last inspection report dated on 19-05-2022, concluded with Acceptable level of compliance with GMP.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter which specifies Tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16359 dated 14-06-2021
	Details of fee submitted	PKR Rs.20,000/- dated 03-07-2021
	The proposed proprietary name / brand name	VONPRO 10mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Vonoprazan Fumarate eq.to……. 10mg Vonoprazan
	Pharmaceutical form of applied drug	Film coated tablet ; Immediate release tablet
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (P-CAB) (WHO ATC code: A02BC08)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	7's, 14's, 20's
	Proposed unit price	As per S.R.O
	The status in reference regulatory authorities	"Takecab 10mg Tablets" Approved by PMDA
	For generic drugs (me-too status)	"Vonozan 10mg" manufactured by M/s Getz Pharmaceuticals, Karachi.
	Name and address of API manufacturer.	Vonprazan Fumarate: M/s. Beijing THTD Pharmaceuticals Technology CO., Ltd. Floor 2nd, No.1 Building, No.29Qingfeng West Road, Zhongguancun Science Park, Daxing, Beijing, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Vonoprazan Fumarate: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months.

		The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies & Comparative Dissolution Profile studies against the reference product of Takecab 10mg Tablets, in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

<table>
<tr><td colspan="5">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="3">Vonoprazan Fumarate: M/s. Beijing THTD Pharmaceuticals Technology CO., Ltd. Floor 2nd, No.1 Building, No.29Qingfeng West Road, Zhongguancun Science Park, Daxing, Beijing, China</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">Vonoprazan Fumarate: B# THTD20191114</td></tr>
<tr><td colspan="2">Description of Pack (Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 65% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>TR-VN10-02</td><td>TR-VN10-03</td><td>TR-VN10-04</td></tr>
<tr><td colspan="2">Batch Size</td><td>2000 Tablets</td><td>2000 Tablets</td><td>2000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>02.2020</td><td>02.2020</td><td>02.2020</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>#</td><td>Documents To Be Provided</td><td colspan="3">Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">Not submitted</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Vonoprazan Fumarate:
GMP certificate submitted was of M/s. Hefei Lifeon Pharmaceuticals co. Ltd. Tangkou Road and Qingluan Road Intersection, Economic and Technological Development ZoneWenqu Road No.446 High Tech Zone Hefei.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP has been submitted.
Vonoprazan Fumarate:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>B# THTD20191114</td><td>THTD20191206</td><td>0.3 Kg</td><td>19-12-2019</td></tr>
</table></td></tr>
</table>

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

Remarks of Evaluator:
Initially firm submitted the data of applied product in which API manufacturer was M/s. *Beijing THTD Pharmaceuticals Technology CO., Ltd. Floor 2nd, No.1 Building, No.29Qingfeng West Road, Zhongguancun Science Park, Daxing, Beijing, China,* while the copy of GMP certificate submitted was of *M/s. Hefei Lifeon Pharmaceuticals Co. Ltd. Tangkou Road and Qingluan Road Intersection, Economic and Technological Development ZoneWenqu Road No.446 High Tech Zone Hefei*. Dossier has been submitted with Dy.no. 16359 dated 14-06-2021 and fee of Rs. 20,000/- dated 03-07-2021. Now, Firm submitted the new data in which the drug substance has been procured from M/s. Jiangxi Synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin Industrial park, Fengxin 330700, Jiangxi Province, P.R China vide invoice no. JXSG220162 dated 31-01-2022 attested by DRAP Karachi. New data has been submitted without any fee.

	Name, address of Applicant / Marketing Authorization Holder	**M/s Bosch Pharmaceuticals (Pvt.) Ltd.,** **Bosch House221, Sector 23, Korangi Industrial area, Karachi**
	Name, address of Manufacturing site.	M/s Bosch Pharmaceuticals (Pvt.) Ltd., Bosch House221, Sector 23, Korangi Industrial area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted last inspection report dated on 19-05-2022, concluded with Acceptable level of compliance with GMP.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter which specifies Tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.23373 : 18/08/2022
	Details of fee submitted	Revised data has been submitted without fees
	The proposed proprietary name / brand name	VONPRO 10mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Vonoprazan Fumarate eq.to……. 10mg Vonoprazan
	Pharmaceutical form of applied drug	Film coated tablet ; Immediate release tablet
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (P-CAB)

		(WHO ATC code: A02BC08)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	7's, 14's, 20's
	Proposed unit price	As per S.R.O
	The status in reference regulatory authorities	"Takecab 10mg Tablets" Approved by PMDA
	For generic drugs (me-too status)	"Vonozan 10mg" manufactured by M/s Getz Pharmaceuticals, Karachi.
	Name and address of API manufacturer.	Vonprazan Fumarate: Jiangxi Synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin Industrial park, Fengxin 330700, Jiangxi Province, P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Vonoprazan Fumarate: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies & Comparative Dissolution Profile studies against the reference product of Vociniti Tablet 10mg of M/s. Takeda Pharmaceuticals, in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted validation studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.
STABILITY STUDY DATA		

<table>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="3">Vonoprazan Fumarate: Jiangxi Synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin Industrial park, Fengxin 330700, Jiangxi Province, P.R China.</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">Vonoprazan Fumarate: B# 20210801BD</td></tr>
<tr><td colspan="2">Description of Pack (Container closure system)</td><td colspan="3">Alu-PVDC blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 65% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>T-001</td><td>T-002</td><td>T-0003</td></tr>
<tr><td colspan="2">Batch Size</td><td>2000 Tablets</td><td>2000 Tablets</td><td>2000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>02.2022</td><td>02.2022</td><td>02.2022</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>#</td><td>Documents To Be Provided</td><td colspan="3">Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">Merolinz (Meropenem) 500mg & Merolinz (Meropenem) 1gram (DRB-313) dated Nov - 2021</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Vonoprazan Fumarate:
Copy of GMP issued in the name of M/s. Jiangxi Synergy Pharmaceutical Co., Ltd., valid till 11-03-2025.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP has been submitted.
Vonoprazan Fumarate:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>B# 20210801BD</td><td>JXSG220162</td><td>0.2 Kg</td><td>31-01-2022</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with batch manufacturing record and analytical record.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td><td colspan="3">Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="5">Remarks of Evaluator:
Initially firm submitted the data of applied product in which API manufacturer was M/s. Beijing THTD Pharmaceuticals Technology CO., Ltd. Floor 2nd, No.1 Building, No.29Qingfeng West Road,</td></tr>
</table>

Zhongguancun Science Park, Daxing, Beijing, China, while the copy of GMP certificate submitted was of *M/s. Hefei Lifeon Pharmaceuticals co. Ltd. Tangkou Road and Qingluan Road Intersection, Economic and Technological Development ZoneWenqu Road No.446 High Tech Zone Hefei*.Dossier has been submitted with Dy.no. 16359 dated 14-06-2021 and fee of Rs.20,000/- dated 03-07-2021. Now, Firm submitted the new data in which the drug substance has been procured from M/s. Jiangxi Synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin Industrial park, Fengxin 330700, Jiangxi Province, P.R China vide invoice no. JXSG220162 dated 31-01-2022 attested by DRAP Karachi. New data has been submitted without any fee.

Decision: Approved. Firm shall submit full fee of registration i.e., Rs. 30,000 for submission of revised stability data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

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

63.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bosch Pharmaceuticals (Pvt.) Ltd., Bosch House221, Sector 23, Korangi Industrial area, Karachi**
	Name, address of Manufacturing site.	M/s Bosch Pharmaceuticals (Pvt.) Ltd., Bosch House221, Sector 23, Korangi Industrial area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted last inspection report dated on 19-05-2022, concluded with Acceptable level of compliance with GMP.
	Evidence of approval of manufacturing facility	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	Firm submitted last inspection report dated on 19-05-2022, concluded with Acceptable level of compliance with GMP.
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 16359 dated 14-06-2021
	Details of fee submitted	PKR Rs.20,000/- dated 03-07-2021
	The proposed proprietary name / brand name	VONPRO 20mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Vonoprazan fumarate eq.to …..... 20mg Vonoprazan.
	Pharmaceutical form of applied drug	Film coated tablet ; Immediate release tablet
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (P-CAB) (WHO ATC code: A02BC08)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	14's
	Proposed unit price	As per S.R.O
	The status in reference regulatory authorities	"Takecab 20 Tablets" Approved by PMDA
	For generic drugs (me-too status)	N.A

	Name and address of API manufacturer.	Vonprazan Fumarate: M/s. Beijing THTD Pharmaceuticals Technology CO., Ltd. Floor 2nd, No.1 Building, No.29Qingfeng West Road, Zhongguancun Science Park, Daxing, Beijing, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Vonoprazan Fumarate: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies & Comparative Dissolution Profile studies against the reference product of Takecab 20 Tablets, in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA	
Manufacturer of APIs	Vonoprazan Fumarate: M/s. Beijing THTD Pharmaceuticals Technology CO., Ltd. Floor 2nd, No.1 Building, No.29Qingfeng West Road, Zhongguancun Science Park, Daxing, Beijing, China
API Lot No.	Vonoprazan Fumarate: B# THTD20191114
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

		Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		TR-VN10-02	TR-VN10-03	TR-VN10-04
Batch Size		2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date		02.2020	02.2020	02.2020
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
#	Documents To Be Provided	Status		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Merolinz (Meropenem) 500mg & Merolinz (Meropenem) 1gram (DRB-313) dated Nov - 2021		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Vonoprazan Fumarate: Copy of GMP issued in the name of M/s. Jiangxi Synergy Pharmaceutical Co., Ltd., valid till 11-03-2025.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP has been submitted. Vonoprazan Fumarate:		

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
B# THTD20191114	THTD20191206	0.3 Kg	19-12-2019

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of 3 stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)
Remarks of the Evaluator:		

	Name, address of Applicant / Marketing Authorization Holder	**M/s Bosch Pharmaceuticals (Pvt.) Ltd., Bosch House221, Sector 23, Korangi Industrial area, Karachi**
	Name, address of Manufacturing site.	M/s Bosch Pharmaceuticals (Pvt.) Ltd., Bosch House221, Sector 23, Korangi Industrial area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted last inspection report dated on 19-05-2022, concluded with Acceptable level of compliance with GMP.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter which specifies Tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Initial dy.no. 16360 dated 14-06-2021 later,Dy. No.23374 : 18/08/2022
	Details of fee submitted	Revised data has been submitted
	The proposed proprietary name / brand name	VONPRO 20mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Vonoprazan fumarate eq.to …..... 20mg Vonoprazan.
	Pharmaceutical form of applied drug	Film coated tablet ; Immediate release tablet
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (P-CAB) (WHO ATC code: A02BC08)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	14's
	Proposed unit price	As per S.R.O
	The status in reference regulatory authorities	"Takecab 20 Tablets" Approved by PMDA
	For generic drugs (me-too status)	N.A
	Name and address of API manufacturer.	Vonprazan Fumarate: Jiangxi Synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin Industrial park, Fengxin 330700, Jiangxi Province, P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Vonoprazan Fumarate: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis,

		justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies & Comparative Dissolution Profile studies against the reference product of Takecab 20 Tablets, in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA

Manufacturer of APIs	Vonoprazan Fumarate: Jiangxi Synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin Industrial park, Fengxin 330700, Jiangxi Province, P.R China.		
API Lot No.	Vonoprazan Fumarate: B# 20210801BD		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	02.2022	02.2022	02.2022

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Merolinz (Meropenem) 500mg & Merolinz (Meropenem) 1gram (DRB-313) dated Nov - 2021
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Vonoprazan Fumarate: Copy of GMP issued in the name of M/s. Jiangxi Synergy Pharmaceutical Co., Ltd., valid till 11-03-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP has been submitted. Vonoprazan Fumarate:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
B# 20210801BD	JXSG220162	0.2 Kg	31-01-2022

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of 3 stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports on product testing.

6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

Initially firm submitted the data of applied product in which API manufacturer was M/s. *Beijing THTD Pharmaceuticals Technology CO., Ltd. Floor 2nd, No.1 Building, No.29Qingfeng West Road, Zhongguancun Science Park, Daxing, Beijing, China*, while the copy of GMP certificate submitted was of *M/s. Hefei Lifeon Pharmaceuticals co. Ltd. Tangkou Road and Qingluan Road Intersection, Economic and Technological Development ZoneWenqu Road No.446 High Tech Zone Hefei*.Dossier has been submitted with Dy.no. 16359 dated 14-06-2021 and fee of Rs.20,000/- dated 03-07-2021. Now, Firm submitted the new data in which the drug substance has been procured from M/s. Jiangxi Synergy Pharmaceutical Co., Ltd., Jiangxi Fengxin Industrial park, Fengxin 330700, Jiangxi Province, P. R China vide invoice no. JXSG220162 dated 31-01-2022 attested by DRAP Karachi.New data has been submitted without any fee.

Decision: Approved. Firm shall submit full fee of registration i.e., Rs. 30,000 for submission of revised stability data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

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

DEFERRED CASE OF PREVIOUS MEETING:

64.	Name, address of Applicant / Marketing Authorization Holder	M/s ICI Pakistan Limited 32/2A, Phase-III, Industrial Estate, Hattar KPK-Pakistan
	Name, address of Manufacturing site.	M/s ICI Pakistan Limited 32/2A, Phase-III, Industrial Estate, Hattar KPK-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23338 dated 26/08/2021
	Details of fee submitted	PKR 30,000/-: dated 26/07/2021 Slip no. 6527173771
	The proposed proprietary name / brand name	Mepronam Injection 1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains Meropenem Trihydrate USP equivalent to 1000mg anhydrous Meropenem
	Pharmaceutical form of applied drug	Powder for solution for injection or infusion
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Meronem IV 1g Composition: Each vial contains meropenem trihydrate equivalent to 1g anhydrous meropenem Dosage Form: Injection or Infusion Route of Administration: IV Country: UK Manufacturer: Pfizer Limited
	For generic drugs (me-too status)	Merem Injection 1g

		Each vial contains: - Meropenem……. .... 1mg Manufacturer: Global Pharmaceuticals Pvt. Ltd. Pack Size: 1's
	GMP status of the Finished product manufacturer	GMP Certificate No. F.11-6/2020-27 Valid till 13/04/2022
	Name and address of API manufacturer.	SHENZHEN HAIBIN PHARMACEUTICAL CO., LTD. Add: 2003 Shenyan Road, 518081 Shenzhen Yantian District, Guangdong, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Meropenem Trihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity RRT with 0.45 and RRT with 1.9, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (MT110204, MT110301, MT110302)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is MERONEM INJECTION TM IV 1g Pfizer Pakistan Limited by performing quality tests (Identification, Assay, Sterility, BET, Impurity, and Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including Specificity, Accuracy, Repeatability, Linearity and Range

STABILITY STUDY DATA			
Manufacturer of API	SHENZHEN HAIBIN PHARMACEUTICAL CO., LTD. Add: 2003 Shenyan Road, 518081 Shenzhen Yantian District, Guangdong, P.R. China.		
API Lot No.	612-6878R		
Description of Pack (Container closure system)	25cc transparent moulded glass vial, Maroon color flip off seal. Rubber stopper 20mm		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	TI-001	TI-002	TI-003
Batch Size	2409 Packs	2409 Packs	2409 Packs

Manufacturing Date	01-2017	01-2017	01-2017
Date of Initiation	04-01-2017	13-01-2017	31-01-2017
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. GD20190927 issued by CFDA valid till 03/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of ADC attested invoice HBINV16187 dated 2-12-2016
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	NA

Remarks OF Evaluator:

Sr.no.	Observations/Shortcomings	Reply of the Firm
1.	Scientific justification for using an entirely different formula for calculation of assay results of drug substance from that specified in USP monograph.	Firm has replied that "Meropenem for Injection is a sterile mixture of Meropenem & Sodium Carbonate which is received in bulk form in sterile sealed containers. The formula given in USP is for single dose container and the one used by the firm is for the analysis and release of bulk raw material received in sterile containers which are further dispensed into single dose containers seeing release potency of relevant lot.
2.	Provide the detailed procedure used for determination of content of sodium as per USP along with the evidence of availability of atomic absorption spectrophotometer.	Initially firm replied that "since Meropenem for Injection is received as a ready to fill sterile material and as no further compounding/processing is involved therein the material, so bulk raw material is released for filling based on seeing satisfactory test results of Sodium Content from the CoA of Manufacturer". Later firm submitted the response that the test for Content of Sodium foreseen by USP has been performed through titrimetric analysis of Sodium Carbonate content, as the only source of Sodium in Meropenem for Injection (Sterile Bulk) is due to the presence of Sodium Carbonate and procedure for the determination has been attached for reference. However as per USP test for sodium content should be performed on atomic absorption spectrophotometer.
3.	The USP monograph under the assay method specifies that sample	Firm replied that "in practice, test samples are kept on hold for 2hrs before injecting into

	should be hold for 1-2 hours at 25± 1°C before testing, while your method does not mention the same. Justify how your method could be considered as complying with USP monograph.	chromatograph, the specific step was missing in analytical procedure and has been added again considering USP Specifications".
4.	Which diluent has been used for the preparation of sample and standard solution. The statement mentioned in sample and standard preparation that "make up the volume with same diluent" did not clarify the type of diluent.	Firm replied that "by same diluent means, the diluent which is being initially taken for dissolving the weighed quantity for standard and sample preparation".
5.	Justify the flow rate of 1.0ml/min as mentioned in the method verification studies for the assay test of drug substance, since USP recommends flow rate to be 1.5ml/min.	The adjustment in flow rate (1.5ml/min) to obtain retention time between 6.0 – 8.0minute was done as per the recommendation of USP. Adjustment in flow rate has been there till USP 42 (NF37), (*Copy of monograph is attached as Annex-I*). This study was also performed seeking guidance from USP monograph on *Chromatography (621), System Suitability, under Flow rate*, where for only Isocratic Elution it is stated that an adjustment can be made in flow rate up to ±50%.
6.	Justify the test of specificity under the verification studies of the drug substance in which you have calculated the percentage of recovery, while as per the ICH guidance "*For chromatographic procedures, representative chromatograms should be used to demonstrate specificity and individual components should be appropriately labelled".* Justify how this test is considered to be the test of specificity in the light of scientific guidelines.	Firm has replied that "For specificity in method verification, we used previously spiked sample solution, where the peak purity (unaffectedness of main analyte) has been demonstrated through recovery method. The recovery was performed just to check the disparity (if any) in the peak area of main analyte in sample solution with respect to working standard solution. The concentration of standard and sample solutions was kept same so that we can determine peak purity through ratio of peak areas. The peak purity (average recovery) of main analyte observed during specificity was around 99%.
7.	Provide the data along with the raw data sheet reflecting the sample, standard and placebo preparation procedure for performance of precision, specificity and accuracy parameters.	Raw data has been submitted reflecting the reflecting the sample, standard and placebo preparation procedure for performance of precision, specificity and accuracy parameters.
8.	Scientific justification for not performing the test of sodium content for the analysis of the drug substance.	Since Meropenem for Injection is received as a ready to fill sterile material and as no further compounding/processing is involved therein the material, so bulk raw material is released for filling based on seeing satisfactory test results of Sodium Content from the CoA of Manufacturer. Later firm submitted the response that the test for Content of Sodium foreseen by USP has been performed through titrimetric analysis of Sodium Carbonate content, as the only source of Sodium in Meropenem for Injection (Sterile Bulk) is due to the presence of Sodium Carbonate and procedure for the determination has been attached for reference.

		However as per USP test for sodium content should be performed on atomic absorption spectrophotometer.
9.	Compatibility Compatibility studies for the dry powder for injections with its diluent shall be performed as per the instructions provided in individual label of the drug product.	Compatibility Studies data of Sterile Meropenem for injection with its Diluent (Sterilized Water for Injection) has been submitted and were performed on single reconstituted vial stored in refrigerator (2-8°C) up to 24hrs.
10.	Manufacturing Process Development Process validation and/or evaluation Justify how 1382mg of meropenem as trihydrate blended with sodium carbonate contains 1000mg of meropenem.	The fill weight, 1382mg, is with respect to release potency of lot used in the batch along-with overage. Scientific justification of using of overage of active ingredient has not been provided by the firm.
11.	Justify the weight variation limit ±10% along with the pharmacopoeial reference.	The weight variation limit, ±10%, for powder for parenteral preparation (single dose) has been adopted from British Pharmacopoeia, *Appendix XII C. Consistency of Formulated Preparations, Uniformity of Weight (Mass).*
12.	Control of Drug Product Specification Justify why the test of content of sodium is not included in the specifications of drug product.	Firm has submitted that the meropenem for Injection is received as a ready to fill sterile material which is further dispensed into single dose containers (under aseptic conditions) based on release potency of the relevant lot. So, in this case, the test parameters which are previously performed on bulk raw material are also performed on filled vials with few additional tests required for filled vials. The bulk material is released based on satisfactory test results of Sodium Content from the CoA of Manufacturer.
13.	As per the provided procedure of performing assay, content of vial has been reconstituted in distilled water clarification is required that either the prescribed diluent for reconstitution of meropenem injection is distilled water.	Firm has replied that "For analysis, the diluent for reconstitution of meropenem for injection is distilled water which is actually purified water meeting the requirement of test parameters mentioned in USP pharmacopeia. Whereas for parenteral administration, the prescribed diluent is sterilized water for injection (10ml ampoule), which is packed in the carton". However, as per USP
14.	As per the provided procedure of performing assay, content of vial has been reconstituted in distilled water clarification is required that either the prescribed diluent for reconstitution of meropenem injection is distilled water.	Firm has submitted the reply that "For analysis, the diluent for reconstitution of meropenem for injection is distilled water which is actually purified water meeting the requirement of test parameters mentioned in USP pharmacopeia. Whereas for parenteral administration, the prescribed diluent is sterilized water for injection (10ml ampoule), which is packed in the carton."
15.	The USP monograph under the assay method specifies that sample should be hold for 1-2 hours at 25± 1°C before testing, while your method does not mention the same. Justify how your method could be considered as complying with USP monograph.	Firm has submitted the reply that "*In practice, test samples are kept on hold for 2hrs before injecting into chromatograph, the specific step was missing in analytical procedure and has been added again considering USP Specifications."*

16.	Provide the detailed procedure used for determination of content of sodium as per USP along with the evidence of availability of atomic absorption spectrophotometer.	Firm has submitted the reply that "*In case of filled product, for sodium content, we follow the released bulk raw material which is released for filling based on seeing satisfactory test results of Sodium Content from the CoA of Manufacturer*".
17.	Reference Standards or Materials Provide COA of primary / secondary reference standard including source and lot number.	Firm has submitted the COA of working standard of ICI Pakistan Ltd. of Meropenem with sodium carbonate having assay limit of NLT 78% calculated on dried basis standardized against USP reference standard of meropenem.
18.	Following data has not been provided along with the stability data: • Reference of previous approval of applications with stability study data of the firm (if any) • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• Firm has submitted Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Reference of previous approval of applications with stability study data of the firm (if any) (when the name of Manufacturer was M/s. Cirin Pharmaceuticals (Pvt.) Ltd., Hattar KPK). • Firm has submitted the audit trail report of merpen injection while applied product is Mepronam Injection.

Decision of 316th meeting of Registration Board:

- Justification of submitted fill weight per vial with reference to the actual sodium content in the drug substance.
- Evidence of purchase of Atomic absorption spectrophotometer along with Installation Qualification (IQ) and Operational Qualification (OQ) reports as well as performance data for sodium content test as per USP monograph on upcoming commercial batch of product already registered on contract manufacturing.

Response of the Firm:

Justification of submitted fill weight per vial with reference to the actual sodium content in the drug substance. Firm submitted the calculation of filled weight per vial and according to the document filled weight per vial is calculated by using actual potency of meropenem (on as basis) and the formula used was *Fill Weight Calculation (Per vial): Label Claim x 100/Actual Potency*.Filled weight per vial should be 1382mg for 1000mg strength.

Evidence of purchase of Atomic absorption spectrophotometer along with Installation Qualification (IQ) and Operational Qualification (OQ) reports as well as performance data for sodium content test as per USP monograph on upcoming commercial batch of product already registered on contract manufacturing.
Firm has submitted the invoice number SL1 108293 dated 17-07-2022 as an evidence of purchase of atomic absorption spectrophotometer. Firm submitted the Installation Qualification (IQ) and Operational Qualification (OQ) reports and performance data of sodium content test of two commercial batches which are already registered on contract manufacturing with ICI Hattar. Data of Batch no. 2C471, 2C474 has submitted.

Decision: Approved.

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

65.	Name, address of Applicant / Marketing Authorization Holder	M/s ICI Pakistan Limited 32/2A, Phase-III, Industrial Estate, Hattar KPK-Pakistan
	Name, address of Manufacturing site.	M/s ICI Pakistan Limited 32/2A, Phase-III, Industrial Estate, Hattar KPK-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23337 dated 26/08/2021
	Details of fee submitted	PKR 30,000/-: dated 26/07/2021 Slip no. 216786002
	The proposed proprietary name / brand name	Mepronam Injection 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains Meropenem Trihydrate USP equivalent to 500mg anhydrous Meropenem
	Pharmaceutical form of applied drug	Powder for solution for injection or infusion
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Meronem IV 500mg Composition: Each vial contains meropenem trihydrate equivalent to 500 mg anhydrous meropenem Dosage Form: Injection or Infusion Route of Administration: IV Country: UK Manufacturer: Pfizer Limited
	For generic drugs (me-too status)	Merem Injection 500 mg Each vial contains: - Meropenem……. .... 500mg Manufacturer: Global Pharmaceuticals Pvt. Ltd. Pack Size: 1's
	GMP status of the Finished product manufacturer	GMP Certificate No. F.11-6/2020-27 Valid till 13/04/2022
	Name and address of API manufacturer.	SHENZHEN HAIBIN PHARMACEUTICAL CO., LTD. Add: 2003 Shenyan Road, 518081 Shenzhen Yantian District, Guangdong, P.R.China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Meropenem Trihydrate is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity RRT with 0.45 and RRT with 1.9, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions:

		Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MT110204, MT110301, MT110302)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is MERONEM INJECTION TM IV 500mg Pfizer Pakistan Limited by performing quality tests (Identification, Assay, Sterility, BET, Impurity, and Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including Specificity, Accuracy, Repeatability, Linearity and Range

STABILITY STUDY DATA			
Manufacturer of API	SHENZHEN HAIBIN PHARMACEUTICAL CO., LTD. Add: 2003 Shenyan Road, 518081 Shenzhen Yantian District, Guangdong, P.R. China.		
API Lot No.	612-6878R		
Description of Pack (Container closure system)	15cc clean transparent tubular glass vial with dark blue flip off seal. Rubber Stopper 20mm		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	TI-001	TI-002	TI-003
Batch Size	14454 units	14454 units	14454 units
Manufacturing Date	01-2017	01-2017	01-2017
Date of Initiation	12-01-2017	13-01-2017	26-01-2017
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. GD20190927 issued by CFDA valid till 03/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of ADC attested invoice HBINV16187 dated 2-12-2016
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted the audit trail report of merpen injection while applied product is Mepronam Injection.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no	Observations/Shortcomings	Reply of the Firm
1.	Scientific justification for using an entirely different formula for calculation of assay results of drug substance from that specified in USP monograph.	Firm has replied that "Meropenem for Injection is a sterile mixture of Meropenem & Sodium Carbonate which is received in bulk form in sterile sealed containers. The formula given in USP is for single dose container and the one used by the firm is for the analysis and release of bulk raw material received in sterile containers which are further dispensed into single dose containers seeing release potency of relevant lot.
2.	Provide the detailed procedure used for determination of content of sodium as per USP along with the evidence of availability of atomic absorption spectrophotometer.	Initially firm replied that "since Meropenem for Injection is received as a ready to fill sterile material and as no further compounding/processing is involved therein the material, so bulk raw material is released for filling based on seeing satisfactory test results of Sodium Content from the CoA of Manufacturer". Later firm submitted the response that the test for Content of Sodium foreseen by USP has been performed through titrimetric analysis of Sodium Carbonate content, as the only source of Sodium in Meropenem for Injection (Sterile Bulk) is due to the presence of Sodium Carbonate and procedure for the determination has been attached for reference. However as per USP test for sodium content should be performed on atomic absorption spectrophotometer.
3.	The USP monograph under the assay method specifies that sample should be hold for 1-2 hours at 25± 1°C before testing, while your method does not mention the same. Justify how your method could be considered as complying with USP monograph.	Firm replied that "in practice, test samples are kept on hold for 2hrs before injecting into chromatograph, the specific step was missing in analytical procedure and has been added again considering USP Specifications".
4.	Which diluent has been used for the preparation of sample and standard solution. The statement mentioned in sample and standard preparation that "make up the volume with same diluent" did not clarify the type of diluent.	Firm replied that "by same diluent means, the diluent which is being initially taken for dissolving the weighed quantity for standard and sample preparation".
5.	Validation of analytical procedures Justify the flow rate of 1.0ml/min as mentioned in the method verification studies for the assay test of drug substance, since USP recommends flow rate to be 1.5ml/min.	The adjustment in flow rate (1.5ml/min) to obtain retention time between 6.0 – 8.0minute was done as per the recommendation of USP. Adjustment in flow rate has been there till USP 42 (NF37), (*Copy of monograph is attached as Annex-I*). This study was also performed seeking guidance from USP monograph on *Chromatography (621), System Suitability, under Flow rate*, where for only Isocratic Elution it is stated that an adjustment can be made in flow rate up to ±50%.
6.	Justify the test of specificity under the verification studies of the drug substance in which you have calculated the percentage of recovery, while as per the ICH guidance "*For chromatographic procedures, representative chromatograms should be used to demonstrate specificity and*	Firm has replied that "For specificity in method verification, we used previously spiked sample solution, where the peak purity (unaffectedness of main analyte) has been demonstrated through recovery method. The recovery was performed just to check the disparity (if any) in the peak area of main analyte in sample solution with respect to working standard solution. The concentration of standard and sample solutions was kept same so that we can determine peak purity through

	individual components should be appropriately labelled". Justify how this test is considered to be the test of specificity in the light of scientific guidelines.	ratio of peak areas. The peak purity (average recovery) of main analyte observed during specificity was around 99%.
7.	Provide the data along with the raw data sheet reflecting the sample, standard and placebo preparation procedure for performance of precision, specificity and accuracy parameters.	Raw data has been submitted reflecting the reflecting the sample, standard and placebo preparation procedure for performance of precision, specificity and accuracy parameters.
8.	Scientific justification for not performing the test of sodium content for the analysis of the drug substance.	Since Meropenem for Injection is received as a ready to fill sterile material and as no further compounding/processing is involved therein the material, so bulk raw material is released for filling based on seeing satisfactory test results of Sodium Content from the CoA of Manufacturer. Later firm submitted the response that the test for Content of Sodium foreseen by USP has been performed through titrimetric analysis of Sodium Carbonate content, as the only source of Sodium in Meropenem for Injection (Sterile Bulk) is due to the presence of Sodium Carbonate and procedure for the determination has been attached for reference. However as per USP test for sodium content should be performed on atomic absorption spectrophotometer.
9.	Compatibility studies for the dry powder for injections with its diluent shall be performed as per the instructions provided in individual label of the drug product.	Compatibility Studies data of Sterile Meropenem for injection with its Diluent (Sterilized Water for Injection) has been submitted and were performed on single reconstituted vial stored in refrigerator (2-8°C) upto 24hrs.
10.	Manufacturing Process Development Process validation and/or evaluation Justify how 710mg of meropenem as trihydrate blended with sodium carbonate contains 500mg of meropenem.	The fill weight, 710mg, is with respect to release potency of lot used in the batch along-with overage. Scientific justification of using of overage of active ingredient has not been provided by the firm.
11.	Justify the weight variation limit ±10% along with the pharmacopeial reference.	The weight variation limit, ±10%, for powder for parenteral preparation (single dose) has been adopted from British Pharmacopoeia, *Appendix XII C. Consistency of Formulated Preparations, Uniformity of Weight (Mass).*
12.	As per the filled BMR of trial batches the weight variation has been ranges from 677.67mg to 705.33 mg and objective fill weight was 691. 5mg.Clarification is required regarding the variation in specification of filled weight in different sections of CTD.	Firm has submitted the reply that "*Trial batch was filled in Jan-2017 without any overage with stringent fill weight in order to make assessment of process related critical attributes".*
13.	Control of Drug Product Specification Justify why the test of content of sodium is not included in the specifications of drug product.	Firm has submitted that the meropenem for Injection is received as a ready to fill sterile material which is further dispensed into single dose containers (under aseptic conditions) based on release potency of the relevant lot. So, in this case, the test parameters which are previously performed on bulk raw material are also performed on filled vials with few additional tests required for filled vials. The bulk material is released based on satisfactory test results of Sodium Content from the CoA of Manufacturer.

14.	As per the provided procedure of performing assay, content of vial has been reconstituted in distilled water clarification is required that either the prescribed diluent for reconstitution of meropenem injection is distilled water.	Firm has replied that "For analysis, the diluent for reconstitution of meropenem for injection is distilled water which is actually purified water meeting the requirement of test parameters mentioned in USP pharmacopeia. Whereas for parenteral administration, the prescribed diluent is sterilized water for injection (10ml ampoule), which is packed in the carton".
15.	As per the provided procedure of performing assay, content of vial has been reconstituted in distilled water clarification is required that either the prescribed diluent for reconstitution of meropenem injection is distilled water.	Firm has submitted the reply that "For analysis, the diluent for reconstitution of meropenem for injection is distilled water which is actually purified water meeting the requirement of test parameters mentioned in USP pharmacopeia. Whereas for parenteral administration, the prescribed diluent is sterilized water for injection (10ml ampoule), which is packed in the carton."
16.	The USP monograph under the assay method specifies that sample should be hold for 1-2 hours at 25± 1°C before testing, while your method does not mention the same. Justify how your method could be considered as complying with USP monograph.	Firm has submitted the reply that "*In practice, test samples are kept on hold for 2hrs before injecting into chromatograph, the specific step was missing in analytical procedure and has been added again considering USP Specifications."*
17.	Provide the detailed procedure used for determination of content of sodium as per USP along with the evidence of availability of atomic absorption spectrophotometer.	Firm has submitted the reply that "*In case of filled product, for sodium content, we follow the released bulk raw material which is released for filling based on seeing satisfactory test results of Sodium Content from the CoA of Manufacturer*".
18.	Reference Standards or Materials Provide COA of primary / secondary reference standard including source and lot number.	Firm has submitted the COA of working standard of ICI Pakistan Ltd. of Meropenem with sodium carbonate having assay limit of NLT 78% calculated on dried basis standardized against USP reference standard of meropenem.
19.	Following data has not been provided along with the stability data: • Reference of previous approval of applications with stability study data of the firm (if any) • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• Firm has submitted Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Reference of previous approval of applications with stability study data of the firm (if any) (when the name of Manufacturer was M/s. Cirin Pharmaceuticals (Pvt.) Ltd., Hattar KPK).

Decision of 316th meeting of Registration Board:

- Justification of submitted fill weight per vial with reference to the actual sodium content in the drug substance.
- Evidence of purchase of Atomic absorption spectrophotometer alongwith Installation Qualification (IQ) and Operational Qualification (OQ) reports as well as performance data for sodium content test as per USP monograph on upcoming commercial batch of product already registered on contract manufacturing.

Response of the Firm:

Justification of submitted filled weight per vial with reference to the actual sodium content in the drug substance.

Firm submitted the calculation of filled weight per vial and according to the document filled weight per vial is calculated by using actual potency of meropenem (on as basis) and the formula used was *Fill Weight*

Calculation (Per vial): Label Claim x 100/Actual Potency. Filled weight per vial should be 691.5mg for 500mg strength. Evidence of purchase of Atomic absorption spectrophotometer alongwith Installation Qualification (IQ) and Operational Qualification (OQ) reports as well as performance data for sodium content test as per USP monograph on upcoming commercial batch of product already registered on contract manufacturing. Firm has submitted the invoice number SL1 108293 dated 17-07-2022 as an evidence of purchase of atomic absorption spectrophotometer. Firm submitted the Installation Qualification (IQ) and Operational Qualification (OQ) reports and performance data of sodium content test of two commercial batches which are already registered on contract manufacturing with ICI Hattar. Data of Batch no. 2H862, 2H871 has submitted.
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Stability Cases:

66.	Name and address of manufacturer / Applicant	M/s. Winthrox Laboratories K-219-A,Phase II,S.I.T.E., Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Winnac Fort Eye Drop (Nepafenac 3mg/ml)
	Composition	Each ml contains: Nepafenac…..3mg (Pack size 5ml)
	Diary No. Date of R& I & fee	Dy.No.17893 dated 15-05-2018 Rs. 20,000/- 14-05-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA (Nepafenac ophthalmic suspension, 0.3%, topical ophthalmic, Each mL of Nepafenac ophthalmic suspension, 0.3% contains 3 mg of nepafenac 1.7ml in a 4ml bottle.)
	Me-too status	Ilevro Eye drops (suspension) , pack size: 3ml of M/s. Novartis registered in 278th meeting ,Reg. no. 095874.
	GMP status	19-11-2020 Routine GMP Inspection "overall GMP compliance level is rated as good."

STABILITY STUDY DATA	
Drug	Nepafenac
Name of Manufacturer	M/s. Winthrox Laboratories K-219-A,Phase II,S.I.T.E., Super Highway, Karachi
Manufacturer of API	M/s.Flax Laboratories (756096), Plot No. B-29/1, MIDC Mahad,Village Birwadi,Mahad,Dist. Rigad
API Lot No.	As per invoice attested by DRAP batch no. PSS/1912042 has been imported
Description of Pack (Container closure system)	Plastic bottles of 10ml
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH
Time Period	Real time: Trial-03 (24 months), Trial-04 (6months), Trial-05 (6months) Accelerated: 6 months

Frequency	Trial-03	Trial-04	Trial-05
	Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6,9,12,18,24 (month)	Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6, (month)	Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6, (month)
Batch No.	Trial-03	Trial-04	Trial-05
Batch Size	200 bottles	200 bottles	200 bottles
Manufacturing Date	05-2020	12-2021	12-2021
Date of Initiation	05-05-2020	20-12-2021	20-12-2021
No. of Batches	03		
Date of Submission	26-05-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not provided
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	COA of API from API Manufacturing has been submitted but the COA of API from finished product has not been submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Method used for analysis of API from API Manufacturer has been submitted while the method used for analysis of API from finished product Manufacturer has not been submitted.
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 24 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate for M/s.Flax Laboratories (756096), Plot No. B-29/1, MIDC Mahad,Village Birwadi,Mahad,Dist. Rigad,India issued by Food and Drug Adminstration Maharashtra issued on 13-01-2021 and, valid till 12-01-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice no. AE/19/0436 Dated: 20-01-2020 from M/s.Flax Laboratories (756096), Plot No. B-29/1, MIDC Mahad,Village Birwadi,Mahad,Dist. Rigad,India attested by AD DRAP (Karachi) dated ; 26-02-2020 for Nepafenac Micronized & Sterilized batch no. PSS/1912042.
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	NA

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:<table><tr><td colspan="3">Winnac Forte Eye Drop</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>T-03</td><td>200 bottles</td><td>04-05-2020</td></tr><tr><td>T-04</td><td>200 bottles</td><td>12-12-2021</td></tr><tr><td>T-05</td><td>200 bottles</td><td>12-12-2021</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not submitted</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Yes</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Audit trail of instant product has not been submitted.</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Yes</td></tr>
</table>

- REMARKS OF EVALUATOR

Sr.no.	Shortcoming/Deficiencies	Reply of Firm
1.	Submit reference of previous approval of applications with stability study data of the firm (if available)	Not submitted
2.	Provide certificate of Analysis of API from API Manufacturer, since the COA of API from finished product manufacturer has only submitted with the dossier.	Submitted
3.	Provide method used for analysis of API from API Manufacturer.	Submitted
4.	Submit stability study data of API from API manufacturer	Firm submitted the stability data of 24months, while the stability study duration is of 24months asper the submitted stability summary sheet.
5.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate for M/s.Flax Laboratories (756096), Plot No. B-29/1, MIDC Mahad,Village Birwadi,Mahad,Dist. Rigad,India issued by Food and Drug Adminstration Maharashtra issued on 13-01-2021 and, valid till 12-01-2022.
6.	Provide documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice no. AE/19/0436 Dated: 20-01-2020 from M/s.Flax Laboratories (756096), Plot No. B-29/1, MIDC Mahad,Village Birwadi,Mahad,Dist. Rigad, India attested by AD DRAP (Karachi) dated ; 26-02-2020 for Nepafenac Micronized & Sterilized batch no. PSS/1912042.
7.	Provide protocols followed for conduction of stability study	Submitted
8.	Complete batch manufacturing record of three stability batches, since stability data of trial batch T-03 has only been submitted.	Firm submitted the complete BMR of trial batches T-03,T-04 & T-05.

9.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
10.	Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing, certificate of compliance from shimadzu corporation did not fulfill the requirement.	Audit trail of instant product has not been submitted.
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.	Submitted
12.	Scientific justification is required for setting the pH criteria 7.2-7.7 as specified in the BMR, since the innovator product mentioned that the pH of ophthalmic suspension should be approx. 6.8. Further, the limit of pH mentioned in the specification of product is 6.7-7.6.	Firm stated that we have revised the pH range i.e. 6.7-7.6 in BMR as per the finished product specification of winnac forte eye drop.
13.	Justification is required for using high quantity of Benzalkonium Chloride i.e. 0.1mg/ml, since the innovator product contains 0.05mg of Benzalkonium chloride per ml of ophthalmic suspension.	Firm submitted the reply in which it is stated that due to typographical error we have mentioned 0.1mg/ml of Benzalkonium Chloride instead of 0.05mg /ml
14.	Justify why the test of osmolality, resuspendability, viscosity and Bacterial endotoxin test has not performed/included in the batch release specification of finished product.	Firm submitted the revised batch analysis report in which the test of osmolality, resuspendability, viscosity and Bacterial endotoxin test has been included.

Decision: Approved. Registration letter shall be issued after submission of following documents:

- **Pharmaceutical equivalence report, performed against the innovator product/reference product.**
- **Water loss study of drug product, since the primary container of drug product is LDPE bottles.**
- **Preservative efficacy test of drug product, since the formulation contains Benzalkonium chloride as a preservative.**

PREVIOUSLY DEFERRED CASES OF Form-5

67.	**Name and address of manufacturer / Applicant**	**Bryon Pharmaceuticals (Pvt.) Ltd. 48-Hayatabad Industrial Estate, Peshawar**
	Brand Name +Dosage Form + Strength	Citaglip 50mg Tablet
	Diary No. Date of R& I & fee	(Original Dossier) Dy. No.72 dated 28/03/2012 of Rs.8,000/- (original) Differential fee (original) of Rs.12,000/- submitted on 12/07/2016 Dy.no.237
	Composition	Each Film coated tablet contains: Sitagliptin Phosphate eq. to Sitagliptin….50mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specific
	Pack Size & Demanded Price	As per S.R. O
	Approval Status of Product in Reference Regulatory Authorities	Januvia 50mg film-coated tablets Approved by MHRA of UK
	Me-too Status	Duvel 50mg Tablet by M/s Martin Dow Ltd. (Reg No. 079615)

	GMP Status	GMP Inspection conducted on 17/10/2019 and concluded with the following remarks "The firm may be considered operating in satisfactory level of cGMP compliance".
	Remarks of the Evaluator.	• Scientific justification of using 3% overage of active ingredient in the formulation. • firm applied with in house-specification while the formulation is available in official monograph of USP and BP.
	Decision of 312th meeting of Registration Board	Deferred for scientific justification of using 3% overage in the formulation.
	Response of the Firm	Firm submitted the response in which they informed that the overage usage in formulation was by mistake, we hereby submit revised and rectified formulation with fee of Rs. 7,500/- deposit vide slip no. 40222285095 dated 05-11-202. Further requested to change specification from in-house to USP.
	Decision: Approved with USP specifications. **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
68.	**Name and address of manufacturer / Applicant**	**Bryon Pharmaceuticals (Pvt.) Ltd. 48-Hayatabad Industrial Estate, Peshawar**
	Brand Name +Dosage Form + Strength	Citaglip 100mg Tablet
	Diary No. Date of R& I & fee	(Original Dossier) Dy. No.69 dated 28/03/2012 of Rs.8,000/- (original) Differential fee (original) of Rs.12,000/- submitted on 12/07/2016 Dy.no.236
	Composition	Each Film coated tablet contains: Sitagliptin Phosphate eq. to Sitagliptin….100mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specific
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Sitagliptin 100 mg film-coated tablets by M/s Laboratories Biogaran (MHRA Approved)
	Me-too Status	A-Glip 100mg Tablets by M/s Atco Laboratories (Reg.No.053098)
	GMP Status	GMP Inspection conducted on 17/10/2019 and concluded with the following remarks "The firm may be considered operating in satisfactory level of cGMP compliance".
	Remarks of the Evaluator.	• Scientific justification of using 3% overage of active ingredient in the formulation. • Initially, firm applied with in house-specification while the formulation is available in official monograph of USP and BP.
	Decision of 312th meeting of Registration Board	Deferred for scientific justification of using 3% overage in the formulation.
	Response of the Firm	Firm submitted the response in which they informed that the overage usage in formulation was by mistake, we hereby submit revised and rectified formulation with fee of Rs. 7,500/- deposit vide slip no. 40222285095 dated 05-11-202. Further requested to change specification from in-house to USP.
	Decision: Approved with USP specifications. **Firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

Case 01; Registration applications of locally manufactured New License / New Section on form 5F.

Firm has submitted copy of Acknowledgment of receipt of application for grant of DML by way of formulation to M/s Nagarsons Pharmaceuticals dated 19-02-2021 from Secretary Central Licensing Board. The letter specifies that CLB in its 278th meeting held on 10th and 11th December 2020 has approved the grant of DML in the name of M/s Nagarsons Pharmaceuticals for following sections:

1. Tablet (General)
2. Tablet (Psychotropic)
3. Capsule (General)
4. Cream /ointment/Lotion/Gel

This is their first application in the Cream /ointment/Lotion/Gel section.

69.	Name, address of Applicant / Marketing Authorization Holder	Nagarsons Pharmaceuticals (Pvt.) Ltd., Plot No. 34, Street No NS-2, National Industrial Zone Rawat, Islamabad.
	Name, address of Manufacturing site.	Nagarsons Pharmaceuticals (Pvt.) Ltd., Plot No. 34, Street No NS-2, National Industrial Zone Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17394: dated 14/06/2022.
	Details of fee submitted	PKR 30,000/-: dated 03/06/2022.
	The proposed proprietary name / brand name	Terbinag Cream 1%.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of cream contains: Terbinafine hydrochloride …….. 10mg
	Pharmaceutical form of applied drug	Craem.
	Pharmacotherapeutic Group of (API)	Antifungals.
	Reference to Finished product specifications	JP specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Lamisil Cream 1 %, USFDA Approved.
	For generic drugs (me-too status)	Terbin Cream 1%, Martin Dow Pharmaceutical, Reg. No. 026751.
	GMP status of the Finished product manufacturer	New DML issued w.e.f. 19-02-2021.
	Evidence of section approval.	Cream/ointment/Lotion/Gel (General) section approved vide letter No. F.1-5/2020-Lic dated 19-02-2021.

	Name and address of API manufacturer.	M/S Saptagir Laboratories (Pvt.) Ltd., Sy. No. Parts of 27, 46 & 50 to 56, 502247 Ananthasagar (Vill.), Chegunta (Mandal), Medak (Distt.) Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Terbinafine as hydrochloride is present in USP. Firm has submitted detail of nomenclature, structure, general properties, solubilities, manufacturers, description of manufacturing process and controls, Characterization, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug substance)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (TH0131216, TH0141216 & TH0151216)
	Module-III (Drug Product):	The firm has submitted detail of description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is Limisil 1% cream by Novartis pharma by performing quality tests (Identification, minimum fill & Assay).
	Analytical method validation/verification of product	Method verification studies have been submitted including accuracy, precision, repeatability, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/S Saptagir Laboratories Pvt Ltd. Sy. No. Parts of 27,46 & 50 to 56, Ananthasagar (Vill.), Chegunta (Mandal), Medak (Distt). Telangana, India.		
API Lot No.	TH0180421		
Description of Pack (Container closure system)	White or almost white cream packed in collapsible Aluminum Tube with polyethylene Screw packed in unit carton (10 gram)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 tubes	500 tubes	500 tubes
Manufacturing Date	10-2021	10-2021	10-2021

Date of Initiation	05-10-2021.	05-10-2021.	05-10-2021.
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document. They further submitted that we are newly granted DML holder hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate dated 01-03-2021 in the name of M/S Saptagir Laboratories Pvt Ltd. Sy. No. Parts of 27,46 & 50 to 56, Ananthasagar (V), Chegunta (M), Medak (Distt). Telangana, India issued by the Drug Control Administration Government of Telangana, India. The certificate is unsigned and it is written on it that this document is digitally signed. Signature is not required. Validity; 01-03-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice# 2122/SL/033 dated 21-07-2021) for terbinafine hydrochloride USP B. No. TH180421 with quantity of 25kg attested by Assistant Director I&E, DRAP, Islamabad dated 15-09-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.7	This section has mentioned oral route of administration. Clarification shall be submitted.	Firm has submitted that route of administration is topical.
2.	1.6.5	Signed and valid GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate dated 01-03-2021 in the name of M/S Saptagir Laboratories Pvt Ltd. Sy. No. Parts of 27,46 & 50 to 56, Ananthasagar (V), Chegunta (M), Medak (Distt). Telangana, India issued by the Drug Control Administration Government of Telangana, India. The certificate is unsigned and it is written on it that this document is digitally signed. Signature is not required. Validity; 01-03-2022. ***Valid copy of the GMP certificate of the drug substance is not submitted by the applicant.***
3.	2.3	Table for literature references has mentioned USP and BP monograph for the drug product. Clarification is required.	Firm has submitted that drug product monograph is available in JP only. ***However, no revised table for literature references is submitted by the applicant.***
4.	2.3.R	Complete batch manufacturing record for the stability batches along	***Not submitted by the applicant.***

		with blank production document shall be submitted.	
5.	3.2.S.4.1	Specifications for the drug substance by the finished product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.2	Analytical procedures for the drug substance by the finished product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.3	Verification studies of the drug substance by the finished product manufacturer shall be submitted.	Submitted.
8.	3.2.S.7.3	Assay test has not been provided in the stability studies of the drug substance. Clarification shall be submitted.	Firm has stated that stability studies always include assay test and assay test is already mentioned in the submitted stability studies. ***However, in the submitted stability studies of the drug substance there is no assay test.***
9.	3.2.P.2.2	This section is mentioned for immediate release tablets. Clarification is required.	Firm has submitted that development of formulation of terbinag 1% cream is based on the detailed review and characterization of the reference product Lamisil 1% cream of GSK having FDA number 020980.
10.	3.2.P.5.3	Only three parameters of the validation of the finished product are submitted. Clarification shall be submitted for not conducting robustness and linearity in the validation of the finished product	Firm has submitted that verification studies of compendial methods do not require robustness and linearity studies.
11.	3.2.P.5.4	Batch analysis of the finished product by the finished product manufacturer shall be submitted.	Firm has submitted that batch analysis has already been submitted in the dossier. COA s were not provided in section 3.2p5.4 titled "Batch analysis", whereas in stability studies data analytical record of all time points including initial time point was submitted.
12.	3.2.P.8.1	Stability data sheets shall be as per format approved by the Registration Board with API lot number and total quantity of the finished product.	Firm has only provided the API lot number (TH0180421) and batch size 500 tubes.
13.	3.2.P.8.3	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted that we have performed stability studies using UV and HPLC equipments present in our QC lab. The QC lab have been visited by the panel of inspectors for the grant of DML based on satisfactory performance of these equipments. They further submitted that their HPLC system is not 21 CFR compliant, but they have maintained all log and records using manual logbooks as per the GMP requirements Firm has submitted that the digital data logger's data is already submitted in in other CTD applications of our firm. Since we are new DML and we have placed all products on stability studies in consecutive months therefore, the same data is applicable for all products.

Decision: Approved. Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

- **Firm will also submit Valid copy of the GMP certificate of the drug substance manufacturer, stability studies for the drug substance including assay test and COA's of all the three trial batches by the finished product manufacturer.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case 02; Registration applications of locally manufactured (Human) drugs on Form 5F.

70.	Name, address of Applicant / Marketing Authorization Holder	M/s Genome Pharmaceutical (Pvt.) Ltd., Address: 16/1, Phase IV, Industrial Estate Hattar, Haripur.
	Name, address of Manufacturing site.	M/s Genome Pharmaceutical (Pvt.) Ltd., Address: 16/1, Phase IV, Industrial Estate Hattar, Haripur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24219: dated 02/09/2021.
	Details of fee submitted	PKR 50,000/-: dated 12/04/2021.
	The proposed proprietary name / brand name	P-CAB 10mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate equivalent to vonoprazan …… 10 mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor. ATC code:A02BC08.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	1x 10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Takecab 10 mg Tablets by Takeda Pharmaceutical Company Limited, PMDA Japanapproved.
	For generic drugs (me-too status)	Vonopran 10mg tablets, Shaigan Pharmaceuticals, Reg. No. 110800.
	GMP status of the Finished product manufacturer	GMP certificate issued on 26-06-2020 on the basis of inspection conducted on 15-06-2020.
	Evidence of section approval.	Tablet general section approved vide letter No. F.3-7/95-Lic (Vol-I) dated 19-02-2016.
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin Industrial Park, Fengxin 330700, Jiangxi Province, P.R. China. GMP certificate No.2020002 dated 12-03-2020 in the name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin

		330700, Jiangxi Province, P.R. China issued by Jiangxi API engineering technology research Centre valid till 11-03-2025.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, specifications, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20190801BD, 20190802BD, 20190803BD)
	Module-III (Drug Product):	The firm has submitted detail of description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Takecab Tablets 10 mg by Takeda Pharmaceutical Company Limited by performing quality tests (Identification, Disintegration, Dissolution & Assay). CDP has been performed against the same brand that is Takecab Tablets 10 mg by Takeda Pharmaceutical Company Limited in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API		Jiangxi Synergy Pharmaceutical Co., Ltd.
API Lot No.		20190802BD
Description of Pack (Container closure system)		Primary Container: 10 tablets are packed in Alu-Alu Foil Secondary Container:

	1 blister of Alu-Alu Foil containing 10 film-coated tablets, packed in a printed carton along with a leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6. (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PC10-T001	PC10-T002	PC10-T003
Batch Size	3000 tablets.	3000 tablets.	3000 tablets.
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	17-05-2020	18-05-2020	20-05-2020
No. of Batches	03		

Administrative Portion

	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Valsac 24mg/26 mg Tablets, Valsac 49mg/51 mg Tablets, Valsac 97mg/103 mg Tablets" which was conducted on 10-03-2020, and was presented in 295th meeting of Registration Board (8-11 June, 2020). Following observations were reported in the report: • The HPLC software is 21CFR Compliant. \ • Audit trail reports were available and physically checked Firm has adequate monitoring and controls for stability chambers
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP for M/s Jiangxi Synergy Pharmaceutical Co., Ltd. Issued by Jiangxi API Engineering Technology Research Center valid upto 11-03-2025.
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# JXSG200352) cleared by DRAP Peshawar Office, Pakistan dated 08-04-2020 specifying import 0.4 Kg (Batch# 20190802BD, Mfg. date 05-08-2019).
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

	section	Observations	Response by the firm
	1.3.4	Valid copy of Drug Manufacturing License of finished product manufacturer shall be submitted.	Firm has submitted copy of Drug Manufacturing license w.e.f. 27-10-2020.

	3.2.S.4.2	Injection volume in the assay test of the drug substance provided by the finished product manufacturer is 20µl while that of the drug substance manufacturer is 10 µl. clarify?	Firm has submitted that injection volume of 20µl is selected for analysis due to fixed loop of 20µl in manual rheodyne of HPLC. The same procedure with 20µl is validated in the submitted data.
	3.2.P.2	Justify the qualitative composition of the applied formulation with innovator product.	Firm has submitted that composition of P-Cab 10mg tablets is according to the composition of the innovator's product "Takecab 10mg" and also provided following link; https://www.pmda.go.jp/files/000211075.pdf composition of the applied formulation is same as per innovator product.
		Provide scientific rationale for selection of dissolution parameters including type of apparatus, rpm, dissolution medium, sampling time and the analytical method.	Firm has submitted that Vonoprazan is highly soluble drug substance based on ICH Q6A, which states that the drug substance should be considered highly soluble if it meets the following two conditions; The dissolution profile of all strengths of the dosage form should be rapid i.e. dissolution >80% in 15 minutes at pH 1.2, 4.0 & 6.8. The highest drug product's strength is soluble in 250ml or less of aqueous media over the pH range of 1.2 to 6.8 at 37 ºC ± 1 ºC. As per ICH Q6A, for dosage forms having drug substances falls in above conditions will be considered as highly soluble drugs and do not require development of discriminatory dissolution method/parameter. Generally, a single time point with one medium is acceptable. Comparative dissolution study by Genome the "P-Cab tablets" against the Innovator Product 'Takecab Tablets' Vonoprazan release more than 85% in all three mediums within 15minutes at 50 RPM. Also, the solubility of Vonoprazan is very high throughout the physiological pH range (1.2 to 6.8). The lowest solubility of Vonoprazan is found to be in pH 6.8 as compared to solubility in pH 1.2 (about 16.5mg/ml) & pH 4.5 (8.1mg/ml) i.e. is about 4.7 mg/ml which is greater than the highest strength divided by 250 (20mg/250=0.08mg/ml), so we selected dissolution medium having pH 6.8 as a worst-case scenario. In light of the above discussion and high solubility of drug substance, discriminatory dissolution parameter are not required for Vonoprazan 10mg & 20mg tablets. Therefore, generalized lowest 50RPM with 900ml medium was selected for release and stability studies of the drug product. Based on above literature and studies, we selected dissolution medium having pH 6.8 as a worst-case scenario, since the solubility of Vonoprazan in pH 6.8 is less as compared to solubility in pH 1.2 (about 16.5mg/ml) & pH 4.5 (8.1mg/ml).

			As vonoprazan release in all the three mediums within 15 minutes was more than 85% therefore, we selected the time point i.e. 15 minutes for dissolution.

Decision: Approved.

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

71.	Name, address of Applicant / Marketing Authorization Holder	Horizon Healthcare (Pvt.) Ltd., Plot # 33, Sundar Industrial Estate, Lahore.
	Name, address of Manufacturing site.	Horizon Healthcare (Pvt.) Ltd., Plot # 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☒ Domestic sale. ☐ Export sale. ☐ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No. 29989 dated 03-11-2021.
	Details of fee submitted	PKR 75,000/-: dated 27-10-2021.
	The proposed proprietary name / brand name	Ticlor 60mg Tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ticagrelor …… 60mg.
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Brilinta 60 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Anplag 60mg, PharmEvo (Pvt.) Ltd., Reg. No.093105.
	GMP status of the Finished product manufacturer	GMP certificate No. 103/2020-DRAP (AD-1998036-5147) dated 06-07-2020 issued on the basis of inspection conducted on 18-06-2020 is submitted by the firm.
	Evidence of section approval.	Tablet general section approved vide letter No. F.1-51/2004 Lic dated 07-02-2004.
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China. Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by

		Nantong chemical and Medical industry association valid till 05-05-2022. Certificate has mentioned different drug substances however; the applied drug substance is not mentioned in the certificate.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (140901, 141001 & 141101)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the reference product Anplag 60mg Tablet by Pharma Evo (Pvt.) Ltd., (Batch No: 9H209 Mfg. 07-2019 & Exp. 07-2021) by performing quality tests (Identification, uniformity of weight, Disintegration time, & Assay). CDP has been performed against the same brand that is Anplag 60mg Tablet by Pharma Evo (Pvt) Ltd in in three different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer & polysorbate 80. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China.
API Lot No.	Not mentioned.
Description of Pack (Container closure system)	Aluminum foil/Alu-Alu blisters packed in bleach board unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period		Real time: 06 months Accelerated: 06 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		TGL-001	TGL-002	TGL-003
Batch Size		1500 tablets	1500 tablets	1500 tablets
Manufacturing Date		02-2020	02-2020	02-2020
Date of Initiation		12-02-2020	14-02-2020	15-02-2020
No. of Batches		03		
REQUEST OF EXEMPTION FROM ON SITE INSPECTION				
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.				
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022. Certificate has mentioned different drug substances however; the applied drug substance is not mentioned in the certificate.		
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice number CY118257 dated 04-12-2018 mentioning 0.35kg quantity of ticagrelor, Batch No. RD-TG-201810081 attested by Assistant Director DRAP, Lahore vide No. 3874/2019DRAP dated 20-03-2019.		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks OF Evaluator:

Sr. No.	Section	Observations.	Response by the firm.
1	1.3.4	Valid copy of DML of the drug product manufacturer shall be submitted.	Firm has submitted copy of DML issued on 06-06-2022 w.e.f. 03-02-2019 in the name of M/s Horizon Pharma, Lahore.
2	1.5.6	This section has mentioned innovator specifications while the official monograph is available in BP. Clarification is required.	Firm has submitted that when the Product Project was initiated (2020), The official monograph was not available in British pharmacopeia. So, we followed the Innovator's specifications. So, we will Changed our Analytical method and specification for

			commercial batches according to B.P official monograph 2022.
3	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority shall be submitted. Provided GMP certificate has different drug substances however, the applied drug substance is not included/mentioned in the certificate. Clarification shall be submitted.	Not submitted by the firm. Firm has submitted that the GMP certificate was provided by Drug product manufacturer was right and obtained from Nantong Chanyoo Pharmatech Co., Ltd. but the certificate was mistakenly attached of our other manufacturer which is applied in our other strength 90mg. Provided GMP certificate is not valid as is valid till 05-05-2022. Furthermore, certificate has mentioned different drug substances however; the applied drug substance is not mentioned in the certificate.
4	2.3	Table for literature references has not mentioned any pharmacopoeia neither for the drug substance nor for the drug product while the official monograph for both the drug substance as well as drug product is available in BP. Justification shall be submitted.	Firm has submitted that when the Product Project was initiated (2020), The official monograph of both drug substance and drug product was not available in British pharmacopeia. So, we followed the Innovator's specifications. So, we will Changed our Analytical method and specification for commercial batches according to B.P official monograph 2022. However, no revised table for literature references is provided.
5	3.2.S.4.1	Manufacturer specification are claimed for the drug substance while the official monograph is available in BP. Justification shall be submitted.	Firm has submitted that when the Product Project was initiated (2020), The official monograph of both drug substance and drug product was not available in British pharmacopeia. That's why they used innovator's specifications.
6	3.2.S.4.2	Analytical procedure for the assay test provided by the drug substance manufacturer has no formula for the assay calculation. Clarification shall be submitted. Analytical procedures provided by the drug product manufacturer for assay test is different from the drug substance manufacturer. Clarification shall be submitted. Analytical procedures provided by the drug product manufacturer for assay test is different from the official monograph. Clarification shall be submitted.	Firm has submitted that the Manufacturer prepared the solution of standard and sample in the similar manner as per manufacturer method. So, they calculate the potency as per comparison profile with standard solution. Firm has submitted new analytical method which is similar to the drug substance manufacturer. However, initially submitted analytical method was different from the drug substance manufacturer in respect of mobile phase, wavelength, injection volume etc. When the Product Project was initiated (2020), The official monograph of drug substance was not available in British pharmacopeia. So, we followed the Analytical procedure provided by the manufacturer. Hence, we will Changed our Analytical method and specification for commercial batches according to B.P official monograph 2022.
7	3.2.S.4.4	The reference product literature specifies polymorphic form II for ticagrelor tablets whereas no such declaration has been made in the COA of drug substance.	Firm has submitted that as per Drug Master file of the drug substance, it is clear that Ticagrelor exist as amorphous forms or crystalline form II.

8	3.2.P.2.2	Justification of not performing Pharmaceutical Equivalence & CDP against innovator product shall be submitted. Justification shall be submitted for carrying CDP in polysorbate medium.	Firm has once again submitted the same results of CDP against Anplag while no justification is provided. Firm has submitted that the dissolution method was borrowed from FDA Dissolution Data profile which was 0.2% w/v solution of polysorbate 80 at different time points that was claimed in our dissolution profile.
9	3.2.P.5.1	This section has mentioned in-house specifications while the official monograph of the applied formulation is available in BP. Assay limits and dissolution limits provided by the drug product manufacturer (90-110% & NLT 75% Q in 75 minutes & NLT 80% Q in 60 minutes) are different from official monograph (95-105% & Q = 70% after 45 minutes). Justification shall be submitted.	Firm has submitted that when the Product Project was initiated (2020), The official monograph of drug substance was not available in British pharmacopeia. So, we followed the Analytical procedure provided by the manufacturer. Hence, we will Changed our Analytical method and specification for commercial batches according to B.P official monograph 2022.
10	3.2.P.8.1	Submit stability data sheets as per approved format by the Registration Board with inclusion of API lot number. Details of the API lot number used during the stability study data shall be submitted. Reference of previous approval of applications with stability study data shall be submitted.	Firm has submitted new stability data sheets wherein they have included API lot number in the sheets and new stability data sheets are as per approved format by the Registration Board. No data submitted.
11		Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three six batches of Ticlor 60mg & 90mg tablets.	Firm has submitted that the Drug substance was imported for Ticlor 90mg from Jiangxi Synergy Pharmaceutical Co., Ltd. 400g (0.4 Kg) while our consumption was 324g (0.324 Kg) for three batches (TGH001, TGH002, TGH003) The Drug substance was imported for Ticlor 60mg from Nantong Chanyoo Pharmatech Co., Ltd. 350g (0.35 Kg) while our consumption was 270g (0.270 Kg) for three batches (TGL001, TGL002, TGL003).

Decision: Approved with BP Specifications.

- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Firm will also submit valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

72.	Name, address of Applicant / Marketing Authorization Holder	Horizon Healthcare (Pvt.) Ltd., Plot # 33, Sundar Industrial Estate, Lahore.

	Name, address of Manufacturing site.	Horizon Healthcare (Pvt.) Ltd., Plot # 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☒ Domestic sale. ☐ Export sale. ☐ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No. 32249 dated 25-11-2021.
	Details of fee submitted	PKR 75,000/-: dated 27-10-2021.
	The proposed proprietary name / brand name	Ticlor 90mg Tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ticagrelor …… 90mg.
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Brilinta 90 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Anplag 90mg, PharmEvo (Pvt.) Ltd., Reg. No.089382.
	GMP status of the Finished product manufacturer	GMP certificate No. 103/2020-DRAP (AD-1998036-5147) dated 06-07-2020 issued on the basis of inspection conducted on 18-06-2020 is submitted by the firm.
	Evidence of section approval.	Tablet general section approved vide letter No. F.1-51/2004 Lic dated 07-02-2004.
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China. Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022. Certificate has mentioned different drug substances however; the applied drug substance is not mentioned in the certificate.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (140901, 141001 & 141101)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the reference product Virata 90mg Tablet by CCL Pharmaceuticals, (Batch No: PO95 Mfg. 12-2018 & Exp. 11-2020) by performing quality tests (Identification, uniformity of weight, Disintegration time, & Assay). CDP has been performed against the same brand that is Virata 90mg Tablet by CCL Pharmaceuticals, in in three different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer & polysorbate 80. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China.		
API Lot No.	RD-TG-201810081		
Description of Pack (Container closure system)	Aluminum foil/Alu-Alu blisters packed in bleach board unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TGH-001	TGH-002	TGH-003
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	29-01-2020	30-01-2020	31-01-2020

No. of Batches		03
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022. Certificate has mentioned different drug substances however; the applied drug substance is not mentioned in the certificate.
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice number CY118257 dated 04-12-2018 mentioning 0.35kg quantity of ticagrelor, Batch No. RD-TG-201810081 attested by Assistant Director DRAP, Lahore vide No. 3874/2019DRAP dated 20-03-2019.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section	Observations.	Response by the firm.
1	1.3.4	Valid copy of DML of the drug product manufacturer shall be submitted.	Firm has submitted copy of DML issued on 06-06-2022 w.e.f. 03-02-2019 in the name of M/s Horizon Pharma, Lahore.
2	1.5.6	This section has mentioned innovator specifications while the official monograph is available in BP. Clarification is required.	Firm has submitted that when the Product Project was initiated (2020), The official monograph was not available in British pharmacopeia. So, we followed the Innovator's specifications. So, we will Changed our Analytical method and specification for commercial batches according to B.P official monograph 2022.
3	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority shall be submitted.	Firm has submitted new GMP certificate for M/s Jiangxi Synergi Pharmaceutical co., Ltd. Jiangxi Fengxin Industrial Park, Jingxi province, China issued by Jiangxi API Engineering Technology Research Centre dated 12-03-2020 valid till 11-03-2025. Firm has also submitted another GMP certificate for M/s Jiangxi Synergi Pharmaceutical co., Ltd. Jiangxi Fengxin Industrial Park, Jingxi province, China issued by Fengxin administration for market

		Provided GMP certificate has different drug substances however, the applied drug substance is not included/mentioned in the certificate. Clarification shall be submitted.	regulation People's Republic of China valid till 01-03-2025. This certificate has alos mentioned Ticagrelor API. Firm has submitted that GMP certificate provided in the registration file was mistakenly attached of our other vendor i.e. M/s Nantong Chanyoo Pharmatech Co., Ltd., while the drug substance was used of M/s Jiangxi Synergi Pharmaceutical co., Ltd. So we attached the correct GMP certificate.
4	2.3	Table for literature references has not mentioned any pharmacopoeia neither for the drug substance nor for the drug product while the official monograph for both the drug substance as well as drug product is available in BP. Justification shall be submitted.	Firm has submitted that when the Product Project was initiated (2020), The official monograph of both drug substance and drug product was not available in British pharmacopeia. So, we followed the Innovator's specifications. So, we will Changed our Analytical method and specification for commercial batches according to B.P official monograph 2022. However, no revised table for literature references is provided.
5	3.2.S.4.1	Manufacturer specification are claimed for the drug substance while the official monograph is available in BP. Justification shall be submitted.	Firm has submitted that when the Product Project was initiated (2020), The official monograph of drug substance was not available in British pharmacopeia. So, we followed the specifications provided by the manufacturer.
6	3.2.S.4.2	Analytical procedure for the assay test provided by the drug substance manufacturer has no formula for the assay calculation. Clarification shall be submitted. Analytical procedures provided by the drug product manufacturer for assay test is different from the drug substance manufacturer. Clarification shall be submitted. Analytical procedures provided by the drug product manufacturer for assay test is different from the official	Firm has submitted that the Manufacturer prepared the solution of standard and sample in the similar manner as per manufacturer method. So, they calculate the potency as per comparison profile with standard solution. The Analytical procedure of drug product manufacturer was provided in Registration file was mistakenly attached of our other i.e. vendor Jiangxi Synergy Pharmaceutical co., Ltd while the drug substance was used of 'Nantong Chanyoo Pharmatech Co., Ltd. Following attachments has attached of this manufacturer; Commercial Invoice No. JXSG181028 dated 03-12-2018 mentioning 0.40 kg quantity of Ticagrelor batch No. 20180504T attested by AD I&E, DRAP Lahore vide No. 4051/2019DRAP dated 22-03-2019. Stability data of drug substance (accelerated and real time for batch No. 20170601T, 20170602T & 20170603T.) Analytical method procedure and specifications of both Drug substance manufacturer and Drug Product Manufacturer COA of Manufacturer COA from Drug Product Manufacturer Standard Analytical Procedure. When the Product Project was initiated (2020), The official monograph of drug substance was not available in British pharmacopeia. So, we followed the Analytical procedure provided by the manufacturer. Hence, we will Changed our Analytical method and specification for

		monograph. Clarification shall be submitted.	commercial batches according to B.P official monograph 2022.
7	3.2.S.4.4	The reference product literature specifies polymorphic form II for ticagrelor tablets whereas no such declaration has been made in the COA of drug substance.	As per Drug Master file of the drug substance, it is clear that Ticagrelor exist as amorphous forms or crystalline form II.
8	3.2.P.2.2	Justification of not performing Pharmaceutical Equivalence & CDP against innovator product shall be submitted. Justification shall be submitted for carrying CDP in Polysorbate medium.	Firm has once again submitted the same results of CDP against Vitara while no justification is provided. Firm has submitted that the dissolution method was borrowed from FDA Dissolution Data profile which was 0.2% w/v solution of Polysorbate 80 at different time points that was claimed in our dissolution profile.
9	3.2.P.5.1	This section has mentioned in-house specifications while the official monograph of the applied formulation is available in BP. Assay limits and dissolution limits provided by the drug product manufacturer (90-110% & NLT 75% Q in 75 minutes & NLT 80% Q in 60 minutes) are different from official monograph (95-105% & Q = 70% after 45 minutes). Justification shall be submitted.	Firm has submitted that when the Product Project was initiated (2020), The official monograph of drug substance was not available in British pharmacopeia. So, we followed the Analytical procedure provided by the manufacturer. Hence, we will Changed our Analytical method and specification for commercial batches according to B.P official monograph 2022.
10	3.2.P.8.1	Submit stability data sheets as per approved format by the Registration Board with inclusion of API lot number. Details of the API lot number used during the stability study data shall be submitted. Reference of previous approval of applications with stability study data shall be submitted.	Firm has submitted new stability data sheets wherein they have included API lot number in the sheets and new stability data sheets are as per approved format by the Registration Board. No data submitted.
		Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three six batches of Ticlor 60mg & 90mg tablets.	Firm has submitted that the Drug substance was imported for Ticlor 90mg from Jiangxi Synergy Pharmaceutical Co., Ltd. 400g (0.4 Kg) while our consumption was 324g (0.324 Kg) for three batches (TGH001, TGH002, TGH003) The Drug substance was imported for Ticlor 60mg from Nantong Chanyoo Pharmatech Co., Ltd. 350g (0.35 Kg) while our consumption was 270g (0.270 Kg) for three batches (TGL001, TGL002, TGL003).

Decision: Approved with BP specifications.

- **Registration letter will be issued after submission of fee of Rs. 30,000/- for correction/pre-approval changes, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Firm will also submit valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

73.	Name, address of Applicant / Marketing Authorization Holder	Change of title from; Cirin Pharmaceuticals Pvt. Ltd., 32/2A, Phase III, Industrial Estate, Hattr district Haripur, KPK. To, ICI Pakistan Limited, 32/2A, Phase III, Industrial Estate, Hattar KPK-Pakistan.
	Name, address of Manufacturing site.	ICI Pakistan Limited, 32/2A, Phase III, Industrial Estate, Hattar KPK-Pakistan.
	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Form 5D initial submission; 31-01-2017. Stability data submitted; 05-05-2021. Form 5F Dy. No. 33586 dated 23-12-2021.
	Details of fee submitted	PKR 50,000/-: dated 31-01-2017 (Cirin pharma). 50,000/- fee submitted dated 27-04-2021 for title change from Cirin pharma to ICI Pakistan Limited.
	The proposed proprietary name / brand name	Rilinta 60mg Tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ticagrelor …… 60mg.
	Pharmaceutical form of applied drug	Oral tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	2 x 10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Brilique 60 mg film coated tablets MHRA approved.
	For generic drugs (me-too status)	Hitica 60mg, Highnoon Laboratories, Reg. No. 103570.
	GMP status of the Finished product manufacturer	GMP certificate No.F.11-6/2020-27 dated 21-05-2020 issued on the basis of inspection conducted on 14-04-2020.
	Evidence of section approval.	Tablet general section approved vide letter No. F.3-4/92-Lic (Vol-III)(Pt)dated 16-06-2021.
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures

		and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (RD-TG-201806261, RD-TG-201808021& RD-TG-201810081)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the reference product Anplag 60mg Tablet by Pharma Evo (Pvt.) Ltd., (Batch No: 0H054 Mfg. 07-2020 & Exp. 07-2022) by performing quality tests (Identification, uniformity of weight, Disintegration time, Dissolution & Assay). CDP has been performed against the same brand that is Anplag 60mg Tablet by Pharma Evo (Pvt) Ltd in in three different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer & pH 6.8 Phosphate buffer. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China.		
API Lot No.	RD-TG-201907211.		
Description of Pack (Container closure system)	2 Alu-Alu blisters of 10's orange color round shaped biconvex film coated tablets.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	ST0H012	ST0H013	ST0H014
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	19-09-2020	19-09-2020	19-09-2020
No. of Batches	03		
REQUEST OF EXEMPTION FROM ON SITE INSPECTION			
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.			
Administrative Portion			

	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted a document issued in the name of M/s Nantong Chanyoo Pharmatech Co., Ltd., by the Jiangsu Drug Administration with the title of "Written confirmation for active substances exported to EU". The document confirms that the plant complies with the requirements of the Chinese Good Manufacturing Practice. This written confirmation remains valid till 12-03-2023.
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 No. 00980/2019/DRAP dated 28/10/2019 DRAP (p)/6417 in the name Cirin Pharmaceuticals Pvt. Ltd., 32/2A, Phase III, Industrial Estate, Hattr district Haripur, KPK mentioning 1.90 kg quantity of Ticagrelor attested by Assistant Drug Controller, DRAP, Peshawar.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section	Observation	Response by the firm
1	1.5.6	This section has mentioned innovator specifications while the official monograph is available in BP. Clarification is required.	Firm has submitted that the trial batches of Rilinta (Ticagrelor 60mg) Tablets were developed in August-2020, whereas the monograph for Ticagrelor tablets was published in British Pharmacopoeia in 2022, hence trial batches were developed as per Innovator's Specifications. They further submitted fee 7500 for change of specifications form innovator to BP specification. Deposit Slip# 5247216348 Dated:26.08.2022
2	1.6.5	GMP certificate of the drug substance manufacturer issued by the concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate in the name of M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical Industry Association dated 21-02-2022 valid till 21.02.2026.
3	2.3	Table for literature references has not mentioned any pharmacopoeia neither for the drug substance nor for the drug product while the official monograph for both the drug substance as well as drug product is available in BP. Justification shall be submitted.	Firm has submitted that at the time of development and submission of dossier, neither monograph of drug substance nor drug product was available in any official pharmacopeia.

4	3.2.S.4.4	The reference product literature specifies polymorphic form II for ticagrelor tablets whereas no such declaration has been made in the COA of drug substance.	Firm has submitted that Polymeric form II has been declared by Drug substance manufacturer under section 3.2. S.1.3 General Properties hence it is not mentioned on CoA.
5	3.2.P.2.2	Justification shall be submitted for CDP up to 75 minutes as the BP monograph has mentioned 45 minutes time for dissolution for the ticagrelor tablets. Justification of not performing Pharmaceutical Equivalence & CDP against innovator product shall be submitted.	Firm has submitted that Comparative Dissolution Profile (CDP) up-to 74minutes was performed in the year 2020 considering the time-points as mentioned in FDA Dissolution Database for Ticagrelor tablets, while the monograph of Dissolution test for Ticagrelor tablet published in BP 2022. As per DRAP guidelines, we have performed, Pharmaceutical Equivalence & CDP studies against comparator brand leader in local market, ANPLAG 60mg Tablets (manufactured by PharmEvo Pvt Limited). In addition, the results were found similar and in compliance with quality test parameters.
6	3.2.P.5.1	Innovator specifications are claimed for the finished product while the official monograph is available in BP. Clarification shall be submitted. Assay limits and dissolution limits provided by the drug product manufacturer (90-110% & NLT 75% Q in 75 minutes) are different from official monograph (95-105% & Q = 70% after 45 minutes). Justification shall be submitted.	Referring the response made under point number 1.5.6, it is restated, that the monograph for Ticagrelor tablet was not available in BP-2020 and hence product was developed as per Innovator's Specifications and the same limits had been applied. However, the commercial batches shall be developed and tested as per monograph available in BP-2022.
7	3.2.P.5.6.	Justification of specification are given that specification for this product has been derived in compliance with innovator's specification while official monograph is available in BP.	Refer to the response made under point number 1.5.6
8	3.2.P.8	Reference of previous approval of applications with stability study data of the firm shall be submitted.	Firm has referred to the inspection of their product Dorinem Injection 500mg (Doripenem (as Monohydrate) 500mg): Approved in Registration Board Meeting-291 Date of Investigation: 24-07-2019 Panel members 1.Prof. Dr. Jamshed Ali Khan, Member Central Licensing Board. 2. Dr. Khalid Javed, Director Drug Testing Laboratory, Peshawar. 3. Mr. Atiq Ul Bari, FID/`Assistant Director, DRAP Peshawar.
9	3.2.P.8	Stability data sheets have mentioned 19-09-2020 as date of initiation for the stability studies while the chromatograms have shown 03-09-2020. Clarification shall be submitted.	Firm has submitted that QC received sample of Coated tablets on 03.09.2020 and performed Assay on the same day. Dissolution test was performed on the next day, 04.09.2020 and released batches on 05.09.2020 for blistering and packing. Batches were blistered and packed on 15.09.2020 and stability samples were submitted to QC on 16.09.2020.

			QC placed the sample in the chamber on 19.09.2020 and as per our SOP of stability study, the date of placement of sample is Stability Chamber is the Data of Initiation of Stability Study. The whole activity has been performed well within the normal manufacturing process time.

Decision: Approved with BP specifications.

- **Registration letter will be issued after submission of valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

74.	Name, address of Applicant / Marketing Authorization Holder	Change of title from; Cirin Pharmaceuticals Pvt. Ltd., 32/2A, Phase III, Industrial Estate, Hattar district Haripur, KPK. To, ICI Pakistan Limited, 32/2A, Phase III, Industrial Estate, Hattar KPK-Pakistan.
	Name, address of Manufacturing site.	ICI Pakistan Limited, 32/2A, Phase III, Industrial Estate, Hattar KPK-Pakistan.
	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Form 5D initial submission; 31-01-2017. Stability data submitted; 05-05-2021. Form 5F Dy. No. 33585 dated 23-12-2021.
	Details of fee submitted	PKR 50,000/-: dated 31-01-2017 (Cirin pharma). 50,000/- fee submitted dated 27-04-2021 for title change from Cirin pharma to ICI Pakistan Limited.
	The proposed proprietary name / brand name	Rilinta 90mg Tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ticagrelor …… 90mg.
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	2 x 10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	BRILINTA® 90mg (ticagrelor) film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Bilinta 90mg Tablet, Scilife Pharma, Reg. No. 090782.

	GMP status of the Finished product manufacturer	GMP certificate No.F.11-6/2020-27 dated 21-05-2020 issued on the basis of inspection conducted on 14-04-2020.
	Evidence of section approval.	Tablet general section approved vide letter No. F.3-4/92-Lic (Vol-III) (Pt)dated 16-06-2021.
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (RD-TG-201806261, RD-TG-201808021& RD-TG-201810081)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the reference product Anplag 90mg Tablet by Pharma Evo (Pvt.) Ltd., (Batch No: 0L124 Mfg. 10-2020 & Exp. 10-2022) by performing quality tests (Identification, uniformity of weight, Disintegration time, Dissolution & Assay). CDP has been performed against the same brand that is Anplag 90mg Tablet by Pharma Evo (Pvt) Ltd., in in three different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer & pH 6.8 Phosphate buffer. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China.
API Lot No.	RD-TG-201907211.
Description of Pack (Container closure system)	2 Alu-Alu blisters of 10's yellow color film coated tablets.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 12 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	ST0H015	ST0H016	ST0H017
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	21-09-2020	21-09-2020	21-09-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted a document issued in the name of M/s Nantong Chanyoo Pharmatech Co., Ltd., by the Jiangsu Drug Administration with the title of "Written confirmation for active substances exported to EU". The document confirms that the plant complies with the requirements of the Chinese Good Manufacturing Practice. This written confirmation remains valid till 12-03-2023.
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 No. 00980/2019/DRAP dated 28/10/2019 DRAP (p)/6417 in the name Cirin Pharmaceuticals Pvt. Ltd., 32/2A, Phase III, Industrial Estate, Hattar district Haripur, KPK mentioning 1.90 kg quantity of Ticagrelor attested by Assistant Drug Controller, DRAP, Peshawar.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section	Observation	Response by the firm
1	1.5.6	This section has mentioned innovator specifications while the official monograph is available in BP. Clarification is required.	Firm has submitted that the trial batches of Rilinta (Ticagrelor 60mg) Tablets were developed in August-2020, whereas the monograph for Ticagrelor tablets was published in British Pharmacopoeia in 2022, hence trial batches were developed as per Innovator's Specifications. They further submitted fee 7500 for change of specifications form innovator to BP specification. Deposit Slip# 5247216348 Dated:26.08.2022

2	1.6.5	GMP certificate of the drug substance manufacturer issued by the concerned regulatory authority shall be submitted.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid upto 2-12-2025
3	2.3	Table for literature references has not mentioned any pharmacopoeia neither for the drug substance nor for the drug product while the official monograph for both the drug substance as well as drug product is available in BP. Justification shall be submitted.	Firm has submitted that at the time of development and submission of dossier, neither monograph of drug substance nor drug product was available in any official pharmacopeia.
4	3.2.S.4.4	The reference product literature specifies polymorphic form II for ticagrelor tablets whereas no such declaration has been made in the COA of drug substance.	Firm has submitted that Polymeric form II has been declared by Drug substance manufacturer under section 3.2. S.1.3 General Properties hence it is not mentioned on CoA.
5	3.2.P.2.2	Justification shall be submitted for CDP up to 75 minutes as the BP monograph has mentioned 45 minutes time for dissolution for the ticagrelor tablets. Justification of not performing Pharmaceutical Equivalence & CDP against innovator product shall be submitted.	Firm has submitted that Comparative Dissolution Profile (CDP) up-to 74minutes was performed in the year 2020 considering the time-points as mentioned in FDA Dissolution Database for Ticagrelor tablets, while the monograph of Dissolution test for Ticagrelor tablet published in BP 2022. As per DRAP guidelines, we have performed, Pharmaceutical Equivalence & CDP studies against comparator brand leader in local market, ANPLAG 90mg Tablets (manufactured by PharmEvo Pvt Limited). In addition, the results were found similar and in compliance with quality test parameters.
6	3.2.P.5.1	Innovator specifications are claimed for the finished product while the official monograph is available in BP. Clarification shall be submitted. Assay limits and dissolution limits provided by the drug product manufacturer (90-110% & NLT 75% Q in 75 minutes) are different from official monograph (95-105% & Q = 70% after 45 minutes). Justification shall be submitted.	Referring the response made under point number 1.5.6, it is restated, that the monograph for Ticagrelor tablet was not available in BP-2020 and hence product was developed as per Innovator's Specifications and the same limits had been applied. However, the commercial batches shall be developed and tested as per monograph available in BP-2022.
7	3.2.P.5.6.	Justification of specification are given that specification for this product has been derived in compliance with innovator's specification while official monograph is available in BP.	Refer to the response made under point number 1.5.6
8	3.2.P.8	Reference of previous approval of applications with stability study data of the firm shall be submitted.	Firm has referred to the inspection of their product Dorinem Injection 500mg (Doripenem (as Monohydrate) 500mg): Approved in Registration Board Meeting-291 Date of Investigation: 24-07-2019 Panel members 1.Prof. Dr. Jamshed Ali Khan, Member Central Licensing Board. 2. Dr. Khalid Javed, Director Drug Testing Laboratory, Peshawar.

			3. Mr. Atiq Ul Bari, FID/`Assistant Director, DRAP Peshawar.
9	3.2.P.8.3	Stability data sheets have mentioned 21-09-2020 as date of initiation for the stability studies while the chromatograms have shown 14-09-2020. Clarification shall be submitted.	Firm has submitted that QC received sample of Coated tablets on 03.09.2020 and performed Assay on the same day. Dissolution test was performed on the next day, 04.09.2020 and released batches on 05.09.2020 for blistering and packing. Batches were blistered and packed on 15.09.2020 and stability samples were submitted to QC on 16.09.2020. QC placed the sample in the chamber on 19.09.2020 and as per our SOP of stability study, the date of placement of sample is Stability Chamber is the Data of Initiation of Stability Study. The whole activity has been performed well within the normal manufacturing process time.

Decision: Approved with BP specifications.

- **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

75.	Name, address of Applicant / Marketing Authorization Holder	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26942, dated 29/09/2021.
	Details of fee submitted	PKR 30,000/-: dated 04/06/2021.
	The proposed proprietary name / brand name	Nebicard 2.5 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Nebivolol as hydrochloride ……... 2.5mg
	Pharmaceutical form of applied drug	Blue color, round, biconvex core tablets, break line on one side and plain from other.
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective ATC code: C07AB
	Reference to Finished product specifications	Inhouse Specifications.

	Proposed Pack size	10's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	BYSTOLIC® (nebivolol) 2.5mg, 5mg, 10mg & 20mg tablets, USFDA approved
	For generic drugs (me-too status)	Nebix Tablet 2.5 mg, Highnoon laboratories, Reg. No. 062776,
	GMP status of the Finished product manufacturer	GMP certificate issued on 25-04-2019 on the basis of inspection conducted on 07-03-2019. Not valid.
	Evidence of section approval.	Not provided.
	Name and address of API manufacturer.	Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug Substance)	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 48 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. (Batch No. D5283-15-002, D5283-15-003 & D5283-15-004)
	Module-III (Drug Product):	The firm has submitted detail of description & composition, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against Nebix 2.5mg tablet, Batch No. 193546 manufactured by M/s Highnoon Laboratories limited by performing tests (Description, Average weight of tablets, Hardness, Disintegration time, Dissolution & Assay). CDP has been performed against the same brand that is Nebix 2.5mg tablet manufactured by M/s Highnoon Laboratories limited in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China		
API Lot No.	D5304-19-002R.		
Description of Pack (Container closure system)	Nabicard Tablet for commercial use is available in Alu-PVC 110 mm blisters sealed with Aluminium foil (hard temper, 30-50µm, dull side protective) of 10'S. Each Blister is packed in printed sale carton along with information leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SNV00112P	SNV00212P	SNV00312P
Batch Size	5000 tablets.	5000 tablets.	5000 tablets.
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	15-12-2020	15-12-2020	15-12-2020
No. of Batches	03		

Administrative Portion

	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. IT/E/API/10/2018 in the name of Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China valid up to 01-12-2020 issued by Eudra GMP is provided. Copy of GMP certificate No. ZJ200047 in the name of Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China issued by Zhejiang Medical Product Administration valid till 28-06-2023 is submitted.
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted. Invoice No. HH2020887, mentioning a quantity: 0.175 kg with Batch No. D5304-19-002R with date of approval by DRAP: 14-05-2020.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing.
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks OF Evaluator:

Sr. No.	Section	Observation	Response by the firm

	1.3	Valid copy of DML and evidence of approval of manufacturing facility of finished product manufacturer shall be submitted. Valid copy of GMP certificate of the finished product manufacturer shall be submitted.	Firm has provided copy of DML w.e.f. 22-07-2015. They also provided copy of a letter received in DRAP on 13-07-2020 for grant of renewal of DML. However, Valid DML is not provided. GMP certificate No. 84/2021-DRAP (AD-386964298-1196) dated 01-11-2021 issued on the basis of inspection conducted on 14-09-2021 is submitted.
	3.2.S.4.3	Verification studies of drug substance performed by the finished product manufacturer shall be submitted.	Submitted.
	3.2.S.4.4	Justification shall be submitted for quantity of the drug substance as COA of the drug substance provided by the finished product manufacturer has mentioned quantity of 0.18 kg while the clearance certificate has mentioned 0.175 kg.	Firm has submitted that it was typographic error and also provided corrected COA.
	3.2.P.2	Justification shall be submitted regarding the Qualitative composition of the applied formulation as Polysorbate 80 and SLS are not included in applied composition which are otherwise included in innovator formulation i.e. Bystolic.	Firm has submitted that their composition is according to the innovator, it was typographical error. Compatibility study is also attached. They also provided new pharmaceutical development wherein they have included Polysorbate 80 and SLS in the composition of the applied formulation. However, in the initially submitted dossier Polysorbate 80 and SLS are not included in applied composition.
	3.2.P.2.2.1	Justification for not performing CDP against the innovator product. CDP has mentioned 15mg of prolong release tablets of M/s Highnoon laboratories. Clarify. USFDA dissolution data base has recommended sampling time of 10, 20, 30 and 45 minutes while the time points selected by the applicants are 15, 30, 45 & 60 minutes. Justification is required.	No reply submitted against this point. No reply submitted against this point. Firm has submitted new CDP studies in three different mediums as per reference of USFDA dissolution data base against Nebix 2.5mg, Batch No. 203502 manufactured by M/s Highnoon laboratories. The values of f2 are in acceptable range.
	3.2.P.5.1	Applied product has dissolution specifications of NLT 80% after 45 minutes while the chemistry review of the innovator product has mentioned 15 minutes. Justification is required. Water content and content uniformity tests are performed by the innovator while the applicant has not performed both the mentioned test on finished product. Clarification is required.	Firm has submitted that dissolution test is performed as per FDA guidelines and the dissolution time specified is 10, 20, 30, 45 minutes. However, FDA dissolution guidelines are for the release pattern while the chemistry review of the innovator product has mentioned 15 minutes for dissolution of the applied formulation.

	3.2.P.8.	Reference of previous approval of applications with stability study data of the firm shall be submitted. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted. Firm has submitted chromatograms for the applied formulation. However, submitted chromatograms have shown that retention time in some chromatograms is between 4-5 minutes while the retention time in some chromatograms is around 2 minutes for the same salt i.e. Nebivolol HCl. While the analytical method for both the dissolution and assay have same chromatographic conditions. The submitted chromatograms are inconsistent and have variation independent of concentration i.e. peak area for different concentrations not correlatable with respective strengths of 2.5mg, 5mg & 10mg. Multiple batch numbers and multiple strength are mentioned on same chromatograms due to which it could not be confirmed that for which strength the same chromatogram is submitted. Furthermore, the chromatograms are blurred and even some are not visible.
	3.2.P.8.3	Raw data sheets for assay test & dissolution test of the finished product shall be submitted.	Submitted.
	3.2.R.1.2	Blank production document shall be submitted.	Not submitted.
		Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three trial batches.	Firm has submitted that quantity used in all three batches of Nebivolol 2.5mg, 5mg & 10mg is 0.0137 kg, 0.02725 kg & 0.0545 kg respectively. While quantity of the drug substance imported is 0.175kg. they further submitted that they have used the free sample quantity of 0.100kg of same lot during the manufacturing and testing process. They have also provided invoice for the same but no clearance is for free sample. Firm as manufactured three trial batches each of 5000 tablets. After the potency adjustments, total quantity of drug substance used per tablet is 2.75mg. 5000 X 3 = 15000 tablets. 15000 X 2.75 = 41.25 gm Total quantity used in the three trial batches is 41.25gm

			Furthermore, clearance of the free sample is also not given.

Decision: Registration Board decided to defer the case for the following points:

i. **Justification shall be submitted regarding the Qualitative composition of the applied formulation as batch formula and submitted executed BMR's have shown that Polysorbate 80 and SLS are not included in applied composition which are otherwise included in innovator formulation i.e. Bystolic.**

ii. **Justification for dissolution specifications of the applied formulation shall be submitted as the applied formulation has dissolution specifications of NLT 80% after 45 minutes while the innovator product has mentioned NLT 80% in 15 minutes.**

iii. **Justification shall be submitted regarding the submitted chromatograms as submitted chromatograms have shown that retention time in some chromatograms is between 4-5 minutes while the retention time in some chromatograms is around 2 minutes for the same salt i.e. Nebivolol HCl. While the analytical method for both the dissolution and assay have same chromatographic conditions for the above mentioned salt.**

iv. **Justification shall be submitted regarding the submitted chromatograms as the submitted chromatograms are inconsistent and have variation independent of concentration i.e. peak area for different concentrations not correlatable with respective strengths of 2.5mg, 5mg & 10mg.**

v. **Justification shall be submitted regarding the submitted chromatograms as the submitted chromatograms have multiple batch numbers and multiple strength are mentioned on same chromatograms due to which it could not be confirmed that for which strength the same chromatogram is submitted. Furthermore, the chromatograms are blurred and even some are not visible.**

vi. **Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three strengths and their three trial batches each. As the document submitted for import of the raw material has mentioned 0.175kg quantity of the drug substance. While the submitted Executed BMR's have shown that total of 42.25gm quantity of the drug substance is used in the three trial batches of tablets 2.5mg and 82.50 gm of the drug substance is used in the three trial batches of 5mg tablets and 163.5 gm of the drug substance is used in the three trial batches of 10mg tablets. Total quantity of the drug substance used in all the three strengths of the trial batches is 290gm.**

76.	Name, address of Applicant / Marketing Authorization Holder	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26943, dated 29/09/2021.
	Details of fee submitted	PKR 30,000/-: dated 04/06/2021.
	The proposed proprietary name / brand name	Nebicard 5 mg tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Nebivolol as hydrochloride ……... 5mg
	Pharmaceutical form of applied drug	Orange yellow color, round, biconvex core tablets, break line on one side and plain from other.
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective

		ATC code: C07AB
	Reference to Finished product specifications	In-house Specifications.
	Proposed Pack size	10's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	BYSTOLIC® (nebivolol) 2.5mg, 5mg, 10mg & 20mg tablets, USFDA approved.
	For generic drugs (me-too status)	Nebix Tablet 5 mg, Highnoon laboratories, Reg. No. 062777.
	GMP status of the Finished product manufacturer	GMP certificate issued on 25-04-2019 on the basis of inspection conducted on 07-03-2019. Not valid.
	Evidence of section approval.	Not provided.
	Name and address of API manufacturer.	Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug Substance)	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 48 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. (Batch No. D5283-15-002, D5283-15-003 & D5283-15-004)
	Module-III (Drug Product):	The firm has submitted detail of description & composition, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against Nebix 5mg tablet, Batch No. 210561 manufactured by M/s Highnoon Laboratories limited by performing tests (Description, Hardness, Disintegration time, Dissolution & Assay). CDP has been performed against the same brand that is Nebix 5mg tablet manufactured by M/s Highnoon Laboratories limited in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.

	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China		
API Lot No.		D5304-19-002R.		
Description of Pack (Container closure system)		Nabicard Tablet for commercial use is available in Alu-PVC 110 mm blisters sealed with Aluminum foil (hard temper, 30-50µm, dull side protective) of 10'S. Each Blister is packed in printed sale carton along with information leaflet.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		SNL00112P	SNL00212P	SNL00312P
Batch Size		5000 tablets.	5000 tablets.	5000 tablets.
Manufacturing Date		12-2020	12-2020	12-2020
Date of Initiation		15-12-2020	15-12-2020	15-12-2020
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. IT/E/API/10/2018 in the name of Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China valid up to 01-12-2020 issued by Eudra GMP is provided. Copy of GMP certificate No. ZJ200047 in the name of Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China issued by Zhejiang Medical Product Administration valid till 28-06-2023 is submitted.		
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted. Invoice No. HH2020887, mentioning a quantity: 0.175 kg with Batch No. D5304-19-002R with date of approval by DRAP: 14-05-2020.		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not Submitted		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing.		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)		
Remarks OF Evaluator:				

Sr. No.	Section	Observation	Response by the firm
	1.3	Valid copy of DML and evidence of approval of manufacturing facility of finished product manufacturer shall be submitted. Valid copy of GMP certificate of the finished product manufacturer shall be submitted.	Firm has provided copy of DML w.e.f. 22-07-2015. They also provided copy of a letter received in DRAP on 13-07-2020 for grant of renewal of DML. However, Valid DML is not provided. GMP certificate No. 84/2021-DRAP (AD-386964298-1196) dated 01-11-2021 issued on the basis of inspection conducted on 14-09-2021 is submitted.
	3.2.S.4.3	Verification studies of drug substance performed by the finished product manufacturer shall be submitted.	Submitted.
	3.2.S.4.4	Justification shall be submitted for quantity of the drug substance as COA of the drug substance provided by the finished product manufacturer has mentioned quantity of 0.18 kg while the clearance certificate has mentioned 0.175 kg.	Firm has submitted that it was typographic error and also provided corrected COA.
	3.2.P.2	Justification shall be submitted regarding the Qualitative composition of the applied formulation as Polysorbate 80 and SLS are not included in applied composition which are otherwise included in innovator formulation i.e. Bystolic.	Firm has submitted that their composition is according to the innovator, it was typographical error. Compatibility study is also attached. They also provided new pharmaceutical development wherein they have included Polysorbate 80 and SLS in the composition of the applied formulation. However, in the initially submitted dossier Polysorbate 80 and SLS are not included in applied composition.
	3.2.P.2.2.1	Justification for not performing CDP against the innovator product. USFDA dissolution data base has recommended sampling time of 10, 20, 30 and 45 minutes while the time points selected by the applicants are 15, 30, 45 & 60 minutes. Justification is required.	No reply submitted against this point. Firm has submitted new CDP studies in three different mediums as per reference of USFDA dissolution data base against Nebix 5mg, Batch No. 221679 manufactured by M/s Highnoon laboratories. The values of f2 are in acceptable range.
	3.2.P.5.1	Applied product has dissolution specifications of NLT 80% after 45 minutes while the chemistry review of the innovator product has mentioned 15 minutes. Justification is required.	Firm has submitted that dissolution test is performed as per FDA guidelines and the dissolution time specified is 10, 20, 30, 45 minutes. However, FDA dissolution guidelines are for the release pattern while the chemistry review of the innovator product has mentioned 15 minutes for dissolution of the applied formulation.

		Water content and content uniformity tests are performed by the innovator while the applicant has not performed both the mentioned test on finished product. Clarification is required.	Firm has submitted updated SOP's wherein they have performed the said test on the finished product.
	3.2.P.8.	Reference of previous approval of applications with stability study data of the firm shall be submitted. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted. Firm has submitted chromatograms for the applied formulation. However, submitted chromatograms have shown that retention time in some chromatograms is between 4-5 minutes while the retention time in some chromatograms is around 2 minutes for the same salt i.e. Nebivolol HCl. While the analytical method for both the dissolution and assay have same chromatographic conditions. The submitted chromatograms are inconsistent and have variation independent of concentration i.e. peak area for different concentrations not correlatable with respective strengths of 2.5mg, 5mg & 10mg. Multiple batch numbers and multiple strength are mentioned on same chromatograms due to which it could not be confirmed that for which strength the same chromatogram is submitted. Furthermore, the chromatograms are blurred and even some are not visible.
	3.2.P.8.3	Raw data sheets for assay test & dissolution test of the finished product shall be submitted.	Submitted.
	3.2.R.1.2	Blank production document shall be submitted.	Not submitted.
		Justification regarding the quantity of drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three trial batches.	Firm has submitted that quantity used in all three batches of Nebivolol 2.5mg, 5mg & 10mg is 0.0137 kg, 0.02725 kg & 0.0545 kg respectively. While quantity of the drug substance imported is 0.175kg. they further submitted that they have used the free sample quantity of 0.100kg of same lot during the manufacturing and testing process. They have also provided invoice for the same but no clearance is for free sample. Firm as manufactured three trial batches each of 5000 tablets. After the potency adjustments, total quantity of drug substance used per tablet is 5.5mg.

			5000 X 3 = 15000 tablets. 15000 X 5.5 = 82.50 gm Total quantity used in the three trial batches is 82.50gm Furthermore, clearance of the free sample is also not given.

Decision: Registration Board decided to deferred the case for the following points:

i. **Justification shall be submitted regarding the Qualitative composition of the applied formulation as batch formula and submitted executed BMR's have shown that Polysorbate 80 and SLS are not included in applied composition which are otherwise included in innovator formulation i.e. Bystolic.**

ii. **Justification for dissolution specifications of the applied formulation shall be submitted as the applied formulation has dissolution specifications of NLT 80% after 45 minutes while the innovator product has mentioned NLT 80% in 15 minutes.**

iii. **Justification shall be submitted regarding the submitted chromatograms as submitted chromatograms have shown that retention time in some chromatograms is between 4-5 minutes while the retention time in some chromatograms is around 2 minutes for the same salt i.e. Nebivolol HCl. While the analytical method for both the dissolution and assay have same chromatographic conditions for the above mentioned salt.**

iv. **Justification shall be submitted regarding the submitted chromatograms as the submitted chromatograms are inconsistent and have variation independent of concentration i.e. peak area for different concentrations not correlatable with respective strengths of 2.5mg, 5mg & 10mg.**

v. **Justification shall be submitted regarding the submitted chromatograms as the submitted chromatograms have multiple batch numbers and multiple strength are mentioned on same chromatograms due to which it could not be confirmed that for which strength the same chromatogram is submitted. Furthermore, the chromatograms are blurred and even some are not visible.**

vi. **Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three strengths and their three trial batches each. As the document submitted for import of the raw material has mentioned 0.175kg quantity of the drug substance. While the submitted Executed BMR's have shown that total of 42.25gm quantity of the drug substance is used in the three trial batches of tablets 2.5mg and 82.50 gm of the drug substance is used in the three trial batches of 5mg tablets and 163.5 gm of the drug substance is used in the three trial batches of 10mg tablets. Total quantity of the drug substance used in all the three strengths of the trial batches is 290gm.**

77.	Name, address of Applicant / Marketing Authorization Holder	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26944, dated 29/09/2021.
	Details of fee submitted	PKR 30,000/-: dated 16/06/2021.
	The proposed proprietary name / brand name	Nebicard 10 mg tablet.

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Nebivolol as hydrochloride ……... 10mg
	Pharmaceutical form of applied drug	Light pink color, round, biconvex core tablets, break line on one side and plain from other.
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective ATC code: C07AB
	Reference to Finished product specifications	In-house Specifications.
	Proposed Pack size	10's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	BYSTOLIC® (Nebivolol) 2.5mg, 5mg, 10mg & 20mg tablets, USFDA approved.
	For generic drugs (me-too status)	Nebix Tablet 10 mg, Highnoon laboratories, Reg. No. 062778.
	GMP status of the Finished product manufacturer	GMP certificate issued on 25-04-2019 on the basis of inspection conducted on 07-03-2019. Not valid.
	Evidence of section approval.	Not provided.
	Name and address of API manufacturer.	Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug Substance)	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 48 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. (Batch No. D5283-15-002, D5283-15-003 & D5283-15-004)
	Module-III (Drug Product):	The firm has submitted detail of description & composition, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against Nebix 10mg tablet, Batch No. 200306 manufactured by M/s Highnoon Laboratories limited by performing tests

		(Description, Hardness, Disintegration time, Dissolution & Assay). CDP has been performed against the same brand that is Nebix 10mg tablet, Batch No. 193328 manufactured by M/s Highnoon Laboratories limited in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China		
API Lot No.		D5304-19-002R.		
Description of Pack (Container closure system)		Nabicard Tablet for commercial use is available in Alu-PVC 110 mm blisters sealed with Aluminum foil (hard temper, 30-50µm, dull side protective) of 10'S. Each Blister is packed in printed sale carton along with information leaflet.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		SNL00112P	SNL00212P	SNL00312P
Batch Size		5000 tablets.	5000 tablets.	5000 tablets.
Manufacturing Date		12-2020	12-2020	12-2020
Date of Initiation		15-12-2020	15-12-2020	15-12-2020
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. IT/E/API/10/2018 in the name of Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China valid up to 01-12-2020 issued by Eudra GMP is provided. Copy of GMP certificate No. ZJ200047 in the name of Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China issued by Zhejiang Medical Product Administration valid till 28-06-2023 is submitted.		
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted. Invoice No. HH2020887, mentioning a quantity: 0.175 kg with Batch No. D5304-19-002R with date of approval by DRAP: 14-05-2020.		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not Submitted		

	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing.
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks OF Evaluator:

Sr. No.	Section	Observation	Response by the firm
	1.3	Valid copy of DML and evidence of approval of manufacturing facility of finished product manufacturer shall be submitted. Valid copy of GMP certificate of the finished product manufacturer shall be submitted.	Firm has provided copy of DML w.e.f. 22-07-2015. They also provided copy of a letter received in DRAP on 13-07-2020 for grant of renewal of DML. However, Valid DML is not provided. GMP certificate No. 84/2021-DRAP (AD-386964298-1196) dated 01-11-2021 issued on the basis of inspection conducted on 14-09-2021 is submitted.
	3.2.S.4.3	Verification studies of drug substance performed by the finished product manufacturer shall be submitted.	Submitted.
	3.2.S.4.4	Justification shall be submitted for quantity of the drug substance as COA of the drug substance provided by the finished product manufacturer has mentioned quantity of 0.18 kg while the clearance certificate has mentioned 0.175 kg.	Firm has submitted that it was typographic error and also provided corrected COA.
	3.2.P.2	Justification shall be submitted regarding the Qualitative composition of the applied formulation as Polysorbate 80 and SLS are not included in applied composition which are otherwise included in innovator formulation i.e. Bystolic.	Firm has submitted that their composition is according to the innovator, it was typographical error. Compatibility study is also attached. They also provided new pharmaceutical development wherein they have included Polysorbate 80 and SLS in the composition of the applied formulation. However, in the initially submitted dossier Polysorbate 80 and SLS are not included in applied composition.
	3.2.P.2.2.1	Justification for not performing CDP against the innovator product. USFDA dissolution data base has recommended sampling time of 10, 20, 30 and 45 minutes while the time points selected by the applicants are 15, 30, 45 & 60 minutes. Justification is required.	No reply submitted against this point. Firm has submitted new CDP studies in three different mediums as per reference of USFDA dissolution data base against Nebix 5mg, Batch No. 221679 manufactured by M/s Highnoon laboratories. The values of f2 are in acceptable range.
	3.2.P.5.1	Applied product has dissolution specifications of NLT 80% after 45 minutes while the chemistry review of the innovator product has mentioned 15 minutes. Justification is required.	Firm has submitted that dissolution test is performed as per FDA guidelines and the dissolution time specified is 10, 20, 30, 45 minutes. However, FDA dissolution guidelines are for the release pattern while the chemistry review of the innovator

		Water content and content uniformity tests are performed by the innovator while the applicant has not performed both the mentioned test on finished product. Clarification is required.	product has mentioned 15 minutes for dissolution of the applied formulation. Firm has submitted updated SOP's wherein they have performed the said test on the finished product.
	3.2.P.8.	Reference of previous approval of applications with stability study data of the firm shall be submitted. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted. Firm has submitted chromatograms for the applied formulation. However, submitted chromatograms have shown that retention time in some chromatograms is between 4-5 minutes while the retention time in some chromatograms is around 2 minutes for the same salt i.e. Nebivolol HCl. While the analytical method for both the dissolution and assay have same chromatographic conditions. The submitted chromatograms are inconsistent and have variation independent of concentration i.e. peak area for different concentrations not correlatable with respective strengths of 2.5mg, 5mg & 10mg. Multiple batch numbers and multiple strength are mentioned on same chromatograms due to which it could not be confirmed that for which strength the same chromatogram is submitted. Furthermore, the chromatograms are blurred and even some are not visible.
	3.2.P.8.3	Raw data sheets for assay test & dissolution test of the finished product shall be submitted.	Submitted.
	3.2.R.1.2	Blank production document shall be submitted.	Not submitted.
		Justification regarding the quantity of drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three trial batches.	Firm has submitted that quantity used in all three batches of Nebivolol 2.5mg, 5mg & 10mg is 0.0137 kg, 0.02725 kg & 0.0545 kg respectively. While quantity of the drug substance imported is 0.175kg. they further submitted that they have used the free sample quantity of 0.100kg of same lot during the manufacturing and testing process. They have also provided invoice for the same but no clearance is for free sample. Firm as manufactured three trial batches each of 5000 tablets. After the potency adjustments, total quantity of drug substance used per tablet is 10.9mg. 5000 X 3 = 15000 tablets. 15000 X 10.9 = 163.5gm gm

			Total quantity used in the three trial batches of 10mg is 163.50gm. Furthermore, clearance of the free sample is also not given.

Decision: Registration Board decided to deferred the case for the following points:

i. **Justification shall be submitted regarding the Qualitative composition of the applied formulation as batch formula and submitted executed BMR's have shown that Polysorbate 80 and SLS are not included in applied composition which are otherwise included in innovator formulation i.e. Bystolic.**

ii. **Justification for dissolution specifications of the applied formulation shall be submitted as the applied formulation has dissolution specifications of NLT 80% after 45 minutes while the innovator product has mentioned NLT 80% in 15 minutes.**

iii. **Justification shall be submitted regarding the submitted chromatograms as submitted chromatograms have shown that retention time in some chromatograms is between 4-5 minutes while the retention time in some chromatograms is around 2 minutes for the same salt i.e. Nebivolol HCl. While the analytical method for both the dissolution and assay have same chromatographic conditions for the above mentioned salt.**

iv. **Justification shall be submitted regarding the submitted chromatograms as the submitted chromatograms are inconsistent and have variation independent of concentration i.e. peak area for different concentrations not correlatable with respective strengths of 2.5mg, 5mg & 10mg.**

v. **Justification shall be submitted regarding the submitted chromatograms as the submitted chromatograms have multiple batch numbers and multiple strength are mentioned on same chromatograms due to which it could not be confirmed that for which strength the same chromatogram is submitted. Furthermore, the chromatograms are blurred and even some are not visible.**

vi. **Justification regarding the drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three strengths and their three trial batches each. As the document submitted for import of the raw material has mentioned 0.175kg quantity of the drug substance. While the submitted Executed BMR's have shown that total of 42.25gm quantity of the drug substance is used in the three trial batches of tablets 2.5mg and 82.50 gm of the drug substance is used in the three trial batches of 5mg tablets and 163.5 gm of the drug substance is used in the three trial batches of 10mg tablets. Total quantity of the drug substance used in all the three strengths of the trial batches is 290gm.**

78.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32251 dated 25-11-2021
	Details of fee submitted	PKR 30,000/-: dated 02-11-2021
	The proposed proprietary name / brand name	Synflex 275mg tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Naproxen sodium ……275mg
	Pharmaceutical form of applied drug	Film-coated tablet

	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti-Rheumatic Products, Non-Steroids. M01A.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	20's & 30's.
	Proposed unit price	As per DPC.
	The status in reference regulatory authorities	Trust Naproxen (naproxen sodium 275mg) film coated tablet, TGA approved.
	For generic drugs (me-too status)	Vimov Tablet 275mg, Cirin Pharmaceuticals., Reg. No. 096132.
	GMP status of the Finished product manufacturer	GMP certificate issued 11-06-2020 on the basis of inspection conducted on 07-04-2019.
	Evidence of section approval.	Tablet (general) section approved vide letter No. F. 2-6/86-Lic (Vol-V) dated 30-07-2018.
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited, D.No. 8-2-337, Road No. 3 Banjara Hills, Telangana State India. **Manufacturing Site.** Industrias Quimicas Falcon de Mexico, S.A. de C.V Km. 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec, Morelos, México.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batch No. ANKA00240A, ANKA00258A & ANKA00259A.
	Module-III (Drug Product):	The firm has submitted detail of description & composition of the drug product, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Innovator product that is Apranax Tablet 275mg Batch No. E0169F01, Exp. Date 03-2022 manufactured by Atnahs Pharma Netherlands by performing quality tests (Identification, weight variation, Disintegration, Assay, Dissolution). CDP has been performed against the same brand that is Apranax Tablet 275mg by Atnahs Pharma Netherlands in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.

	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API	Dr. Reddy's Laboratories Limited, D.No. 8-2-337, Road No. 3 Banjara Hills, Telangana State India. **Manufacturing Site.** Industrias Quimicas Falcon de Mexico, S.A. de C.V Km. 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec, Morelos, México.			
API Lot No.	2101000095 (ANNA00467B) & 2007000010 (ANNA00301B)			
Description of Pack (Container closure system)	Alu/PVC blisters packed in unit carton (2x10's)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	NPD-T-1454-S.		NPD-T-1470-S.	NPD-T-1471-S.
Batch Size	5000 tablets		5000 tablets	5000 tablets
Manufacturing Date	20-04-2021		28-04-2021	28-04-2021
Date of Initiation	04-05-2021		04-05-2021	04-05-2021
No. of Batches	03			
REQUEST OF EXEMPTION FROM ON SITE INSPECTION				
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.				
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Pirfedow Tablets 267mg which was approved in 297th Meeting of Registration Board held on 12th – 15th January 2021 Inspection was conducted on 04th January, 2020. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 203300CT110178 in the name of Industrias Quimicas Falcon de Mexico, S.A. de C.V Km. 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec, Morelos, México issued by Federal commission for the protection against Sanitary Risks (COFEPRIS); PIC/S member since 2018 is provided by the applicant & Valid up to 09-April-2023.		
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# OS3612128407 Dated: 30-09-2020 from Dr. Reddy's Laboratories Limited, mentioning 7,938.600 kg quantity of Naproxen Sodium USP with different batch number		

		(also having B. No. ANNA00467B, 39 x 50kg) cleared by DRAP Karachi office dated 26-10-2020. Firm has submitted copy of invoice (invoice# OS3612105345 Dated: 18-06-2020 from Dr. Reddy's Laboratories Limited, mentioning 4,000.00 kg quantity of Naproxen Sodium USP with different batch number (also having B. No. ANNA00301B, 28 x 50kg) cleared by DRAP Karachi office dated 30-06-2020.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
	1.3.4	Valid copy of GMP certificate of the drug product manufacturer shall be submitted.	Firm has submitted routine GMP inspection report dated 20-10-2021 wherein it is concluded that M/s Martin Dow Limited is considered to be operating at Good level of compliance with cGMP guidelines as per Drugs Act, 1976 and DRAP Act 2012 and rules framed there under. Firm has submitted that we have applied for renewal of GMP certificate, and we are expecting to receive the GMP certificate soon.
	1.6.5	GMP certificate for the drug substance manufacturer has mentioned Industrias Quimicas Falcon de Mexico, S.A. de C.V Km. 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec, Morelos, México while the invoice has mentioned Dr. Reddy's Laboratories Limited, D. No. 8-2-337, Road No. 3 Banjara Hills, Telangana State India. Clarification of relationship shall be submitted between these two.	Dr. Reddy's Laboratories Limited is the administrative headquarters and Industrias Quimicas Falcon de Mexico is their manufacturing site. This clarification is mentioned in the 3.2.S.2.1 of DMF. 3.2.S.2.1 of DMF has mentioned that Industrias Quimicas Falcon de Mexico, S.A. de C.V is subsidiary of Dr. Reddy's Laboratories Limited.
	2.3	Table for literature references has mentioned that drug product is not available in any pharmacopoeia while the official monograph is available in USP. Clarification shall be submitted.	Firm has submitted that table for Literature reference shows all the pharmacopeias that the drug product is available in. They provided new table for literature references for both the drug substance and drug product.
	3.2.S.7	Stability studies of the drug substance has mentioned assay test by HPLC while the specification and analytical procedure has mentioned titration method. Clarification shall be submitted.	Firm has submitted that the drug substance manufacturer performed Assay test by Titration Method in the DMF but the provided stability data in DMF was on Zone-II i.e. 25°C ± 2°C, 60% ± 5% RH (attached herewith as reference) and tested according to Method No. CV0484. However, on our request the drug substance manufacturer provided the stability data on Zone-IV -B

			wherein the Assay is performed via HPLC method according to Method No. CV0694 which is more reliable and stringent than Titration. Also, we have requested the drug substance manufacturer to provide the Analytical Method with HPLC method No. CV0694 which will be subsequently submitted to your esteemed authority.

Decision: Approved.

- **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case 03; Registration applications of Imported (Human) drugs on Form 5F.

79.	Name, address of Applicant / Importer	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.
	Details of Drug Sale License of importer	License No: 1126. Address: B-23-C, S.I.T.E., Karachi-75700, Pakistan Address of Godown: AGP Limited, B-23-C, S.I.T.E., Karachi. Validity: 21-09-2021. Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of wholesale by of manufacturer, importer or indenter.
	Name and address of marketing authorization holder (abroad)	Mylan Laboratories Limited, Plot No. 11,12 & 13, Indore Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur - 454775, Dist.- Dhar, Madhya Pradesh India.
	Name, address of manufacturer(s)	Mylan Laboratories Limited, Plot No. 11,12 & 13, Indore Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur - 454775, Dist.- Dhar, Madhya Pradesh India.
	Name of exporting country	India.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP certificate (No. 7/2014) dated 21-Dec-2018 issued by Food and Drug Administration, Madhya Pradesh, India, for Ricovir-EM (Emtricitabine 200mg/ Tenofovir Disopproxil Femerate 300mg Tablet). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 17-Dec-2021. **GMP:** Firm has submitted copy of legalized GMP certificate No. 07/2014 in the name of Mylan Laboratories Limited, Plot No. 11,12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur - 454775, Dist.- Dhar, Madhya Pradesh India issued by Food and Drug Administration, Idgah Hills, Bhopal (M.P) India. Validity is 21-11-2021.

		Firm has also submitted notarized copy of GMP Certificate No. OGYEI/49552/2017 in the name of Mylan Laboratories Limited, Plot No. 11,12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur - 454775, Dist.- Dhar, Madhya Pradesh India issued by National Institute of Pharmacy and nutrition, Hungary on the basis of inspection conducted on 17-08-2018 valid for three years **WHO Prequalification:** The product is WHO prequalified (Reference Number: HA417)
	Details of letter of authorization / sole agency agreement	**Letter of Authorization:** Firm has submitted original, legalized & product specific letter of Authorization from Mylan Laboratories Limited, having its corporate office at House No. 8-2-293/82/J-III, Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad, India. The letter specifies that the manufacturer appoints M/s AGP Limited, B-23-C, S.I.T.E., Karachi to register their products in Pakistan. The authorization letter is valid till 16-Apr-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26351: dated 22-09-2021.
	Details of fee submitted	PKR 150,000/-: 08-09-2021.
	The proposed proprietary name / brand name	Ricovir-EM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Emtricitabine …….…… 200mg Tenofovir Disoproxil Fumarate ……. 300mg (Innovator's Specification)
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antivirals for treatment of HIV infections, combinations ATC code: J05AR03
	Reference to Finished product specifications	In house.
	Proposed Pack size	28's, 30's & 100's.
	Proposed unit price	As fixed by DRAP.
	The status in reference regulatory authorities	TRUVADA® 200mg/300mg (emtricitabine and tenofovir disoproxil fumarate) tablets, USFDA approved.

	For generic drugs (me-too status)	Tenofo-EM 200mg/300mg Tablet, Getz Pharma, Reg # 076090.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Emtricitabine:** Active drug substance Emtricitabine is being manufactured in Mylan Laboratories Limited - Bulk pharmaceutical chemical production plants at Telangana and Andhra Pradesh India. Manufacturing, testing, packing and release operations have been performed independently in respective manufacturing sites. Aurore Pharmaceuticals Private Limited (Unit-1) # Plot Nos. 35, 36, 38 to 40, 49 to 51, Phase IV, IDA, Jeedimetla Hyderabad - 500055 Telangana, India. *# Formerly known as Mylan Laboratories Limited (Unit-3) (B. No. 25502723,25502724,25502725)* Mylan Laboratories Limited (Unit-2) (Alternative Manufacturing Unit) Survey No. 10 / 42, Gaddapotharam Kazipally Industrial Area Sangareddy District, Telangana India, Pin – 502319. *(B. No. 27054083, 27054084, 27054251)* Mylan Laboratories Limited (Unit-7) (Alternative Manufacturing Unit) Plot No. 14, 99 & 100, IDA, Pashamylaram Phase-II Patancheru, Sangareddy District – 502307 Telangana, India. (B. No. 25512756, 25512757, 25512758) Mylan Laboratories Limited (Unit-9) (Alternative Manufacturing Unit) Plot No. 5, Road No.12, J.N. Pharma City, Tadi Village, Parawada Mandal Visakhapatnam – 531021 Andhra Pradesh, India. *(B. No. 27060065, 27060066, 27060067)* **Tenofovir Disoproxil Fumerate:** Active drug substance Tenofovir Disoproxil Fumarate is being manufactured in Mylan Laboratories Limited - Bulk pharmaceutical chemical production plants at following manufacturing sites; Mylan Laboratories Limited (Unit-1) Survey No. 10/42, Gaddapotharam Kazipally Industrial Area, Sangareddy District 502319 Telangana, India. Mylan Laboratories Limited (Unit-8)

		G Chodavaram, Poosapatirega Mandal Vizianagaram District – 535204 Andhra Pradesh, India. (B. No. 25503327, 25503328, 25503329) Mylan Laboratories Limited (Unit-10) Plot No. 86, Ramky Pharma City (India) Ltd, SEZ, JN Pharma City, Parawada Mandal, Visakhapatnam – 531019 Andhra Pradesh, India (B. No. 20040262, 20040329, 20040330)
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Emtricitabine** Firm has submitted stability study data of 3 batches of API at accelerated, long term & alternative long-term conditions. Stability data for Mylan Laboratories Ltd (Unit-3) The Accelerated stability is conducted at 40°C ± 2°C / 75 + 5% RH for 06 months. The Long-term stability is conducted at 25°C ± 2°C / 60% ± 5 % RH for 60 months. (Batch No. EMT-III/003/06/U-III, EMT-III/004/06/U-III, EMT-III/005/06/U-III) Stability data for Mylan Laboratories Ltd (Unit-2) The Accelerated stability is conducted at 40°C ± 2°C / 75 + 5% RH for 06 months. Alternative Long-term stability is conducted at 30 ± 2°C / 75 ± 5% RH for 60 months. (Batch No. 25501697, 25501698, 25501699) Stability data for Mylan Laboratories Ltd (Unit-9) The Accelerated stability is conducted at 40 ± 2°C / 75% + 5% RH for 06 months. The Long-term stability is conducted at 25°C ± 2°C / 60% ± 5% RH for 36 months. (Batch No. 27060065, 27060066, 27060067) Stability data for Mylan Laboratories Ltd (Unit-7) The Accelerated stability is conducted at 40°C ± 2°C / 75% + 5% RH for 06 months. The Long term stability is conducted at 25°C ± 2°C / 60% ± 5% RH for 12 months. (Batch No. 25512756, 25512757, 25512758) **Tenofovir Disoproxil Fumerate;** Stability data for Mylan Laboratories Ltd (Unit-1) The stability studies conducted at 30 ± 2°C / 65 ± 5% RH for 06 months & at 25 ± 2°C / 60 ± 5% RH for 24 months. *(B. No. 25504422, 25504482, 25504429)*

		Stability data for Mylan Laboratories Ltd (Unit-8) The accelerated stability is conducted at 30 ± 2°C / 75 ± 5% RH for 6 months The real time stability is conducted at 25 ± 2°C / 60 ± 5% RH for 24 months. B. No. 25503327, 25503328, 25503329) Stability data for Mylan Laboratories Ltd (Unit-10) The stability is conducted at 30 ± 2°C / 65 ± 5% RH for 6 months. The real time stability is conducted at 25 ± 2°C / 60 ± 5% RH for 24 months. (B. No. 2550774, 25502808, 25502828)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted bioequivalence studies of their formulation (B. No. ETFA537002) with innovator product i.e. Truvuda 300/200mg tablets manufactured by Gilead Sciences, USA batch No. FDC065 Firm has also submitted CDP against innovator product i.e. Truvuda 300/200mg tablets manufactured by Gilead Sciences, USA batch No. FDC065 in three different mediums of 0.1N HCl (official release media), pH 4.5 acetate buffer & pH 6.8 phosphate buffer.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle pack.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH for 36 months. (b. No. 3061657, 3061658, 3061659)

Evaluation by PEC:

Sr. No.	Section	Observation	Response by the firm
1	3.2.S.4.3 & 3.2.P.5.3	Analytical method validation reports for both the drug substances i.e. Emtricitabine tenofovir disoproxil fumarate and finished product are by matrix laboratories limited. Clarification shall be submitted regarding the matrix laboratories whether it is finished product manufacturer or verification studies of the drug substance by the finished	Firm has submitted that name of the company was changed from M/s Matrix Laboratories Limited to M/s Maylan Laboratories Limited on 5th October, 2011. Therefore, few documents with matrix header submitted in Ricovir-EM tablet dossier, as these were prepared/compiled before the change of company name from Matrix to Maylan. *Firm has submitted a notarized document from Government of India – Ministry of Corporate affairs Registrar of Companies,*

		product manufacturer shall be submitted.	*Andhra Pradesh wherein it is certified that Matrix laboratories limited which was originally incorporated on twenty ninth day of November nineteen hundred eighty four under the companied Act, 1956 (No. 1of 56) as Harren Drugs Private limited having dually passed the necessary resolution in term of section 21 of companies Act, 1956 and the approval of the central Government signified in writing having been accorded thereto under section 21 of the companies Act, 1956, read with Govt. of India, Department of company affairs, New Delhi, Notification No. G.S.R 507 (E) dated 24-06-1985 vide SRN B22016844 dated 05-10-211 the name of the said company in this day changed to Mylan Laboratories limited and this certificate is issued pursuant to section 23(1) of the said Act.*
2	3.2.S.7	Real time stability data and accelerated stability data of the drug substance for different drug substance manufacturers is not as per Zone IV. Justification is required.	Firm has submitted that Ricovir EM tablet is WHO prequalified product (Reference Number: HA417) and is manufactured under control conditions. The storage condition of the drug substance and drug product is approved and maintained throughout shelf life. They further stated that they have requested their principal for the stability data of the drug substance as per zine IV and will submit the data as received.
3	3.2.S.7	For both the drug substances different drug substance manufacturers are mentioned in the dossier. Justification is required or otherwise specify a drug substance manufacturer that shall be used in finished product.	Firm submitted that drug substance used in the manufacturing of the finished product will be from the below mentioned sites; **Tenofovir Disoproxil Fumerate;** Mylan Laboratories Limited (Unit-10) Plot No. 86, Ramky Pharma City (India) Ltd, SEZ, JN Pharma City, Parawada Mandal, Visakhapatnam – 531019 Andhra Pradesh, India. **Emtricitabine;** Mylan Laboratories Limited (Unit-9) Plot No. 5, Road No.12, J.N. Pharma City, Tadi Village, Parawada Mandal Visakhapatnam – 531021 Andhra Pradesh, India.

Decision: Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Case 04; Registration applications of Deferred locally manufactured (Human) drugs on Form 5 with stability data.

80.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals, 387-388, I-9, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Coldene day Tablet
	Diary No. Date of R& I & fee	Dy. No. 16694, R&I Dated 02.10.2017, Rs. 20,000/- (02.10.2017)

	Composition	Each film-coated tablet contains: Acetaminophen ……. 500mg Phenylephrine HCl ……..…..... 5mg
	Pharmacological Group	Analgesic, Non-opioid/ Sympathomimetic Decongestants
	Type of Form	Form 5.
	Finished Product Specification	Manufacturers specification
	Pack size & Demanded Price	1x 10's, 10x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 24-01-2018 and conclusion of inspection was: Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Previous remarks of the Evaluator.	The local and international availability of the applied formulation could not be confirmed.
	Previous decision	Deferred in 284th DRB meeting as the local and international availability of the applied formulation could not be confirmed.
	Evaluation by PEC- XIII	• International reference has been verified as Demazin Cold + Flu Relief tablet of iNova Pharmaceuticals (Australia) Pty Ltd TGA; Australia Approved. • Me- too submitted by the firm has been verified as: Panadol CF Day Caplet (Paracetamol 500mg and Phenylephrine HCl 5mg of M/s GSK, Karachi 094797. • The applied formulation is on stability so firm needs to submit stability studies data of at least three batches at accelerated and real time conditions.
	Decision of 296th meeting of Registration Board.	Registration Board deferred the case for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA			
Drug	Coldene day Tablet 500/5mg		
Name of Manufacturer	M/s Wilson's Pharmaceuticals, 387-388, I-9, Industrial Area, Islamabad.		
Manufacturer of API	Paracetamol: M/s Saakh Pharma (Pvt.) Ltd., C-7/1, NWIZ, Port Qasim Karachi.		
	Phenylephrine Hydrochloride. M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzin China.		
API Lot No.	Paracetamol: 19GN60173	Phenylephrine Hydrochloride. PEH-180101Y1	
Description of Pack (Container closure system)	Alu-Alu strip packed in card box unit carton of 30's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real time: 0,3,6 (months) Accelerated: 0,3,6 (months)		
Batch No.	Trial # 01	Trial # 02	Trial # 03

Batch Size	1500 Tablets	1500 Tablets	1500 Tablet
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	01-09-2019	01-09-2019	01-09-2019
No. of Batches	03		
Date of Submission	11-01-2021 (Dy. No. 1371)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT FOR EXEMPTION

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

S. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to their last inspection report for their product "saferon tablet" Registration Board in its 278th meeting decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Date of Inspection: 10-12-2015, 19-04-2017 & 20-01-2018 Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	<u>Paracetamol:</u> Firm has submitted COA of Paracetamol (Batch # 19GN60173) from M/s Saakh Pharma (Pvt.) Ltd., C-7/1, NWIZ, Port Qasim Karachi. COA from Wilson pharma with Batch No. 19GN60173 has also been been submitted. <u>Phenylephrine Hydrochloride.</u> Firm has submitted COA of Phenylephrine Hydrochloride (Batch # PEH-180101Y1) from M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzin China. COA from Wilson pharma with Batch No. PEH-180101Y1 has also been submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted.
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 12 Months (40°C ± 2°C & 75±5%RH) & long term, 18 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches. <u>Phenylephrine Hydrochloride.</u> The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 48 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches (PEH-160404, PEH-160405 & PEH-160406).
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	<u>Paracetamol:</u> Firm has submitted copy of GMP certificate No. 83/2020-DRAP (K) dated 23-06-2020 of M/s Saakh Pharma (Pvt.) Ltd., C-7/1, NWIZ, Port Qasim Karachi. The certificate is valid till 22-06-2022. <u>Phenylephrine Hydrochloride.</u> Firm has submitted copy of GMP certificate No. GD20150448 of M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzin China issued by China Food and Drug Administration. The certificate is valid till 07-12-2020.

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided copy of attested clearance certificate by AD (I&E), DRAP, Islamabad dated 10-05-2018 confirming import of 308.25gm of Phenylephrine Hydrochloride from M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzin China for Batch No. PEH-180101Y1
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Firm has submitted that ingredients of Coldene day tablets and Panadol Sinus Pain & Congestion relief day & night (innovator brand) are same and no compatibilities of excipients observed with drug during accelerated and real time stability studies. However, in active ingredients of the applied formulation and Panadol Sinus Pain & Congestion relief day tablets are different from each other.
10.	Complete batch manufacturing record of three stability batches.	The firm has manufactured three stability batches of Paracetamol + Phenylephrine hydrochloride Tablets (500mg + 5mg) and has submitted copy of complete batch manufacturing. Details are as under: Coldene day Tablet 500/5mg. Batch No. Bach size Mfg. Date Trial # 01 1500 Tablets 08-2019 Trial # 02 1500 Tablets 08-2019 Trial # 03 1500 Tablets 08-2019
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP against Panadol CF day caplet, Batch No. KU7Y in three different mediums i.e. 0.1N HCl, Acetate Buffer pH 4.5 & Phosphate Buffer pH 6.8 and F2 values for some other formulation have been submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers.

Remarks of the Evaluator:

Sr. No.	Observations	Submission by the firm.
1	Latest GMP certificate/inspection report conducted within last three years of the finished product manufacturer shall be submitted.	Firm has also submitted GMP inspection report dated 24-01-2018. ***Provided GMP inspection report is not within last three years.***
2	COA's of the drug substances by Wilson pharma shall be submitted.	Firm has submitted COA of paracetamol with Batch No. 19GN60173 manufacturing date 01-03-2019 manufactured by M/s Saakh Pharma. Firm also submitted COA of phenylephrine HCl with Batch No. PEH-180101Y1 manufacturing date 27-12-2017 manufactured by M/s Shenzhen Oriental Pharmaceutical Co., Ltd.

3	• Approval of API/ DML/ valid GMP certificate of drug substance manufacturer issued by concerned regulatory authority of country of origin for Phenylephrine hydrochloride shall be submitted. • Analytical method of drug substance from both drug substance manufacturer and Finished Product manufacturer shall be submitted. • Stability study data for Phenylephrine Hydrochloride from the concerned manufacturer shall be submitted.	• Firm has submitted Certificate No.GD190014 issued by Guangdong Food and Drug Administration Wherein M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzin, Guangdong, China complies with the requirements of the Chinees Good Manufacturing Practice (= GMP of EU, WHO/ICH Q7). Certificate is valid till 11-09-2022. **However, Title as per Online Link:** Shenzhen Woland Pharmaceutical Co., Ltd. No. 43, Dakeng Road, Tongle Community, Longgang Street, Longgang District, Shenzhen. **Title as per submitted GMP:** M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzin, Guangdong, China. Submitted. Submitted.
4	Starch pregelatinized maize, Talc purified and stearic acid are used by the innovator product while the applied formulation does not have the same. Innovator product has no sodium starch glycolate (Primojel) while the applied formulation has used Primojel. Clarification is required.	• Firm has submitted that stearic acid & Talcum is a lubricant/glidant and is used for enhancing the flow properties of the material. As our formulated material already had excellent flow properties so we didn't add any lubricant. • Our formulation contains sodium starch glycolate (Primojel) which is derivative of starch and it has excellent disintegrating properties as compared to starch so Primojel was preferred over starch. Moreover, our product is tested and found to be stable chemically and physically with existing formulation.
5	COA of paracetamol used in the stability studies by both the drug substance manufacturer and the finished product manufacturer shall be submitted.	Submitted.
6	Justification for selection of dissolution parameters including dissolution medium, apparatus, time and limits.	Firm has submitted that parameters for dissolution method were developed /selected for the applied formulation as per DRAP guidelines method mentioned in 293rd meeting of the Registration Board held on 06th – 08th January, 2020. Furthermore, dissolution method for above mentioned combination is not available in any pharmacopoeia nor it is available publicly. Therefore, in-house method for dissolution testing was developed and validated. All results observed in stability studies were within the limits.

7	F2 values in comparative dissolution profile for some other product have been submitted. Clarification is required.	Firm has submitted new sheets for the comparative dissolution profile wherein the F2 values for the applied product has been submitted.
8	Executed BMR's have shown three percent of overages of the active ingredients. Justification / Clarification is required.	Firm submitted that 3% overage is included to compensate process losses during manufacturing. The batch size is lab scale of 1500 tablets. The amount of active is paracetamol 500mg, and phenylephrine HCl 5mg and 3% overage cause an increase in amount to 515.0 mg and 5.15 mg respectively. The overage ensures a content uniformity within range as per USP 2018.
Decision of 317th meeting of Registration Board		Deferred for the following reasons; • GMP certificate/last inspection report conducted within last three years. • Scientific justification of 03% overage of the active ingredients in the applied formulation. • Justification for using different excipients from the innovator product.
Submission by the firm.		
GMP certificate/last inspection report conducted within last three years.		GMP certificate No.F.3-96/2022-Addl.Dir.(QA&LT-I) dated August, 2022 on the basis of inspection conducted on 28-07-2022 is submitted by the applicant.
Scientific justification of 03% overage of the active ingredients in the applied formulation.		Firm has submitted an undertaking that when we manufacture the commercial batches of the applied formulation before marketing, we will not add any overages.
Justification for using different excipients from the innovator product.		Firm has submitted an undertaking that when we manufacture the commercial batches of the applied formulation before marketing, we will follow the same formulation as per innovator's product.
Remarks of the Evaluator;		
Decision: Approved with innovator's specifications. • **Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Agenda of Evaluator PEC-XVI

A : Human (Deferred)

81.	Name and address of manufacturer/ Applicant	Metro Pharmaceuticals, plot No. 14, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	PEDIATRO ORAL SOLUTION (Orange Flavor)
	Composition	Each 500 ml contains: Sodium Chloride……..…1.75 mg Trisodium Citrate Dihydrate…… 1.45 mg Potassium Chloride…….0.75 mg Glucose Anhydrous……10 mg

	Diary No. Date of R & I & fee	Dy. No 16491 dated 28-09-2017; Rs.20000/- dated 27-09-2017 ***Dy.NO 25001 dated 09-09-2021 (Duplicate Dossier)***	
	Pharmacological Group	Oral Rehydration Salt/ Electrolyte	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer;s specifications	
	Pack size & Demanded Price	1's * 500 ml, As per SRO	
	Approval status of product in Reference Regulatory Authorities	WHO Standard ORS formulation Sodium Chloride …….3.5 g/ L Potassium Chloride ……1.5 g/L Trisodium Citrate, dihydrate…… 2.9 g/L Glucose Anhydrous …….20.0 g/L	
	Me-too status	Pedinex Oral Rehydration Solution by M/s Nexus Pharma (Pvt) Ltd (Reg#057883)	
	GMP status	Panel GMP inspection of firm was conducted on 21-08-2020 and 02-09-2020 with following conclusion "Keeping in view the above stated observation during inspection, areas visited, documents reviewed it is concluded that M/s Metro Pharmaceuticals, plot No.14, SS-2, National Industrial Zone, Rawat -is operating in compliance to the guidance on GMP as prescribed in the schedule B-II of the Drugs (LR&A) rules 1976 as of today."	
	Remark of the Evaluator [XVI]	Deficiency letter was issued to firm and asked to provide: 1. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board 2. Evidence of facility for terminal sterilization as product is preservative free as per reference product and has a shelf life.	1. Firm has submitted section approval letter mentioning Liquid (Vial) and Liquid (Ampoule) as evidence of terminal sterilization facility and undertaking that they will perform terminal sterilization as per innovator product, along with fee challan No. 4164321868 dated 02/3/22 of 7500/= 2. Evidence of approval of applied formulation in reference regulatory authority/agencies which were adopted by the registration Board is not provided.
	Previous decision of 316th meeting: Deferred for verification of sterilization facility for 500 ml plastic bottle.		
	Reply of the firm	Firm has submitted an undertaking along with reply stating that, Metro Pharmaceuticals hereby declare that each batch of product will be sterilization through irradiation Via Authorized third party named Paras Radiation Company located at 18Km, Multan Road, Lahore. PARAS is providing Gamma Irradiation services to local and multi-national pharmaceutical companies and medical disposable manufacturing industries since 1988.irradiation services for preservation of foods, fruits, vegetables, medical devices, pharmaceutical products and a whole range of other products. The only cold – sterilization services providing and immediate, high degree of sterility and homogeneous penetration. Other Pharmaceutical companies like GSK, Remington, Abbott,	

		ICL, Barret Hodgson and Shiagan also use their facility of sterilization. For details kindly see the below link http://atcop.org.pk/paras/#:~:text+PARAS%20is%20providing%20gamma%irradiation,whole%20range%20of%20other%20products.	
	Remarks of evaluator		
	Decision :Deferred for provision of suitable sterilization facility as sterilization of 500 ml bottle at PARAS is not possible.		
82.	Name and address of manufacturer/ Applicant	Metro Pharmaceuticals, plot No. 14, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.	
	Brand Name + Dosage Form + Strength	PEDIATRO ORAL SOLUTION (Bubble Gum Flavor)	
	Composition	Each 500 ml contains: Sodium Chloride……..…1.75 mg Trisodium Citrate Dihydrate…… 1.45 mg Potassium Chloride…….0.75 mg Glucose Anhydrous……10 mg	
	Diary No. Date of R & I & fee	Dy. No 16502 dated 29-09-2017; Rs.20000/- dated 27-09-2017 ***Dy.NO 25000 dated 09-09-2021 (Duplicate Dossier)***	
	Pharmacological Group	Oral Rehydration Salt/ Electrolyte	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer;s specifications	
	Pack size & Demanded Price	1's * 500 ml, As per SRO	
	Approval status of product in Reference Regulatory Authorities	WHO Standard ORS formulation Sodium Chloride …….3.5 g/ L Potassium Chloride …….1.5 g/L Trisodium Citrate, dihydrate…… 2.9 g/L Glucose Anhydrous …….20.0 g/L	
	Me-too status	Pedinex Oral Rehydration Solution by M/s Nexus Pharma (Pvt) Ltd (Reg#057883)	
	GMP status	Panel GMP inspection of firm was conducted on 21-08-2020 and 02-09-2020 with following conclusion "Keeping in view the above stated observation during inspection, areas visited, documents reviewed it is concluded that M/s Metro Pharmaceuticals, plot No.14, SS-2, National Industrial Zone, Rawat -is operating in compliance to the guidance on GMP as prescribed in the schedule B-II of the Drugs (LR&A) rules 1976 as of today."	
	Remark of the Evaluator [XVI]	Deficiency letter was issued to firm and asked to provide: 1. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board 2. Evidence of facility for terminal sterilization as product is preservative free as per reference product.	1. Firm has submitted section approval letter mentioning Liquid (Vial) and Liquid (Ampoule) as evidence of terminal sterilization facility and undertaking that they will perform terminal sterilization as per innovator product along with fee challan No.40418165530 dated 02/3/22 of 7500/= 2. Evidence of approval of applied formulation in reference regulatory authority/agencies which were adopted by the registration Board is not provided.

	Reply of the firm	Firm has submitted an undertaking along with reply stating that, Metro Pharmaceuticals hereby declare that each batch of product will be sterilization through irradiation Via Authorized third party named Paras Radiation Company located at 18Km, Multan Road, Lahore. PARAS is providing Gamma Irradiation services to local and multi-national pharmaceutical companies and medical disposable manufacturing industries since 1988.irradiation services for preservation of foods, fruits, vegetables, medical devices, pharmaceutical products and a whole range of other products. The only cold – sterilization services providing and immediate, high degree of sterility and homogeneous penetration. Other Pharmaceutical companies like GSK, Remington, Abbott, ICL, Barret Hodgson and Shiagan also use their facility of sterilization. For details kindly see the below link http://atcop.org.pk/paras/#:~:text+PARAS%20is%20providing%20gamma%irradiation,whole%20range%20of%20other%20products.	
	Remarks of evaluator		
	Decision :Deferred for provision of suitable sterilization facility as sterilization of 500 ml bottle at PARAS is not possible.		
83.	Name and address of manufacturer/ Applicant	Metro Pharmaceuticals, plot No. 14, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.	
	Brand Name + Dosage Form + Strength	PEDIATRO ORAL SOLUTION (Lemon Flavor)	
	Composition	Each 500 ml contains: Sodium Chloride……..…1.75 mg Trisodium Citrate Dihydrate…… 1.45 mg Potassium Chloride…….0.75 mg Glucose Anhydrous……10 mg	
	Diary No. Date of R & I & fee	Dy. No 16506 dated 29-09-2017; Rs.20000/- dated 27-09-2017 ***Dy.NO 24999 dated 09-09-2021 (Duplicate Dossier)***	
	Pharmacological Group	Oral Rehydration Salt/ Electrolyte	
	Type of Form	Form-5	
	Finished product Specification	Manufacturer's specifications	
	Pack size & Demanded Price	1's * 500 ml, As per SRO	
	Approval status of product in Reference Regulatory Authorities	WHO Standard ORS formulation Sodium Chloride …….3.5 g/ L Potassium Chloride …….1.5 g/L Trisodium Citrate, dihydrate…… 2.9 g/L Glucose Anhydrous …….20.0 g/L	
	Me-too status	Pedinex Oral Rehydration Solution by M/s Nexus Pharma (Pvt) Ltd (Reg#057883)	
	GMP status	Panel GMP inspection of firm was conducted on 21-08-2020 and 02-09-2020 with following conclusion "Keeping in view the above stated observation during inspection, areas visited, documents reviewed it is concluded that M/s Metro Pharmaceuticals, plot No.14, SS-2, National Industrial Zone, Rawat -is operating in compliance to the guidance on GMP as prescribed in the schedule B-II of the Drugs (LR&A) rules 1976 as of today."	
	Remark of the Evaluator [XVI]	Deficiency letter was issued to firm and asked to provide: 1. Evidence of approval of applied formulation in reference regulatory authorities/agencies	1. Firm has submitted section approval letter mentioning Liquid (Vial) and Liquid (Ampoule) as evidence of terminal sterilization facility and undertaking that they will

		which were adopted by the Registration Board 2. Evidence of facility for terminal sterilization as product is preservative free as per reference product and has a shelf life.	perform terminal sterilization as per innovator product along with fee challan No. 517576680 dated 02/3/22 of 7500/= 2. Evidence of approval of applied formulation in reference regulatory authority/agencies which were adopted by the registration Board is not provided.
	Previous decision of 316th meeting: Deferred for verification of sterilization facility for 500 ml plastic bottle.		
	Reply of the firm	Firm has submitted an undertaking along with reply stating that, Metro Pharmaceuticals hereby declare that each batch of product will be sterilization through irradiation Via Authorized third party named Paras Radiation Company located at 18Km, Multan Road, Lahore. PARAS is providing Gamma Irradiation services to local and multi-national pharmaceutical companies and medical disposable manufacturing industries since 1988.irradiation services for preservation of foods, fruits, vegetables, medical devices, pharmaceutical products and a whole range of other products. The only cold – sterilization services providing and immediate, high degree of sterility and homogeneous penetration. Other Pharmaceutical companies like GSK, Remington, Abbott, ICL, Barret Hodgson and Shiagan also use their facility of sterilization. For details kindly see the below link http://atcop.org.pk/paras/#:~:text+PARAS%20is%20providing%20gamma%irradiation,whole%20range%20of%20other%20products.	
	Remarks of evaluator		
	Decision :Deferred for provision of suitable sterilization facility as sterilization of 500 ml bottle at PARAS is not possible.		
84.	Name and address of manufacturer/ Applicant	Reliance Pharma, Plot No.08, street No. S-8, RCCI Industrial Estate, Rawat, Islamabad.	
	Brand Name + Dosage Form + Strength	RELI-TRIGINE Tablet 50 mg	
	Composition	Each Tablet Contains: Lamotrigine …….50 mg	
	Diary No. Date of R & I & fee	Dy. No 12510 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-convulsant	
	Type of Form	Form-5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	3*10's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA	
	Me-too status	Sportin 50mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 070345)	
	GMP status	GMP status/report within last 3 years not provided	
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Finished Product specification not provided.	

		• All the submitted Form-5 Annexures are without any signature/stamp on plain paper. • GMP inspection report conducted within last 3 years is not provided. • Preregistration variation fee challan.	
	Previous decision of 317th meeting: Deferred for following Shortcomings; 1. Finished Product specification not provided. 2. All the submitted Form-5 Annexures are without any signature/stamp on plain paper. 3. GMP inspection report conducted within last 3 years is not provided. 4. Preregistration variation fee challan.		
	Reply of the firm	Firm has submitted their reply vide dairy No. 23362 dated 18-08-2022 along with form -5 dully signed by QC and Production In charge. Firm has also submitted USP specifications as finished good specification. Firm has also submitted copy DML renewal inspection conducted on 02-06-2022 which stated that the pane; unanimously recommended the approval of DML by way of formulation to M/s Reliance Pharma, plot No.8, street No. s-8, RCCI, Industrial Estate, Rawat with following sections 1- Tablet (General) 2-Capsule (General) 3-Ointment/Cream (General) 4-Gel (General)	
	Remarks of Evaluator	Firm has not submitted preregistration variation fee challan.	
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
85.	Name and address of manufacturer/ Applicant	Reliance Pharma, Plot No.08, street No. S-8, RCCI Industrial Estate, Rawat, Islamabad.	
	Brand Name + Dosage Form + Strength	RELI-TRIGINE Tablet 25 mg	
	Composition	Each Tablet Contains: Lamotrigine …….25 mg	
	Diary No. Date of R & I & fee	Dy. No 12509 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-convulsant	
	Type of Form	Form-5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	3*10's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	MHRA approved.	
	Me-too status	Lamogin Tablets 25mg of M/s Navegal Labs (Reg.# 043972)	
	GMP status	GMP status/report within last 3 years not provided	
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Finished Product specification not provided. • All the submitted Form-5 Annexures are without any	

		signature/stamp on plain paper. • GMP inspection report conducted within last 3 years is not provided. • Preregistration variation fee challan.	
	Previous decision of 317th meeting: Deferred for following Shortcomings; 1. Finished Product specification not provided. 2. All the submitted Form-5 Annexures are without any signature/stamp on plain paper. 3. GMP inspection report conducted within last 3 years is not provided. 4. Preregistration variation fee challan.		
	Reply of the firm	Firm has submitted their reply vide dairy No. 23361 dated 18-08-2022 along with form -5 dully signed by QC and Production In charge. Firm has also submitted USP specifications as finished good specification. Firm has also submitted copy DML renewal inspection conducted on 02-06-2022 which stated that the pane; unanimously recommended the approval of DML by way of formulation to M/s Reliance Pharma, plot No.8, street No. s-8, RCCI, Industrial Estate, Rawat with following sections 1- Tablet (General) 2-Capsule (General) 3-Ointment/Cream (General) 4-Gel (General)	
	Remarks of Evaluator	Firm has not submitted preregistration variation fee challan.	
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
86.	Name and address of manufacturer/ Applicant	Reliance Pharma, Plot No.08, street No. S-8, RCCI Industrial Estate, Rawat, Islamabad.	
	Brand Name + Dosage Form + Strength	RELI-TRIGINE Tablet 100 mg	
	Composition	Each Tablet Contains: Lamotrigine …….100 mg	
	Diary No. Date of R & I & fee	Dy. No 12511 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-convulsant	
	Type of Form	Form-5	
	Finished product Specification	USP specification	
	Pack size & Demanded Price	3*10's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK	
	Me-too status	Epicta 100mg Tablets of M/s Alina Combine Pakistan, Karachi (Reg.# 039081)	
	GMP status	GMP status/report within last 3 years not provided	
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Finished Product specification not provided. • All the submitted Form-5 Annexures are without any signature/stamp on plain paper.	

		• GMP inspection report conducted within last 3 years is not provided. • Preregistration variation fee challan.	
	Previous decision of 317th meeting: Deferred for following Shortcomings; 1. Finished Product specification not provided. 2. All the submitted Form-5 Annexures are without any signature/stamp on plain paper. 3. GMP inspection report conducted within last 3 years is not provided. 4. Preregistration variation fee challan.		
	Reply of the firm	Firm has submitted their reply vide dairy No. 23360 dated 18-08-2022 along with form -5 dully signed by QC and Production In charge. Firm has also submitted USP specifications as finished good specification. Firm has also submitted copy DML renewal inspection conducted on 02-06-2022 which stated that the pane; unanimously recommended the approval of DML by way of formulation to M/s Reliance Pharma, plot No.8, street No. s-8, RCCI, Industrial Estate, Rawat with following sections 1- Tablet (General) 2-Capsule (General) 3-Ointment/Cream (General) 4-Gel (General)	
	Remarks of Evaluator	Firm has not submitted preregistration variation fee challan.	
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
87.	Name and address of manufacturer/ Applicant	Reliance Pharma, Plot No.08, street No. S-8, RCCI Industrial Estate, Rawat, Islamabad.	
	Brand Name + Dosage Form + Strength	SULI-RIDE Tablet 200 mg	
	Composition	Each Tablet Contains: Amisulpride …….200 mg	
	Diary No. Date of R & I & fee	Dy. No 12514 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-psychotics	
	Type of Form	Form-5	
	Finished product Specification	BP specification	
	Pack size & Demanded Price	10's, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Amisulpride 200mg Tablets by M/s Accord-UK Ltd (MHRA Approved)	
	Me-too status	Amiride Tablet 200mg by M/s Shrooq Pharmaceuticals (Pvt) Ltd (Reg#063102)	
	GMP status	GMP status/report within last 3 years not provided	
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Finished Product specification not provided. • All the submitted Form-5 Annexures are without any signature/stamp on plain paper. • GMP inspection report conducted	

		within last 3 years is not provided. • Preregistration variation fee challan.	
	Previous decision of 317th meeting: Deferred for following Shortcomings; 1. Finished Product specification not provided. 2. All the submitted Form-5 Annexures are without any signature/stamp on plain paper. 3. GMP inspection report conducted within last 3 years is not provided. 4. Preregistration variation fee challan.		
	Reply of Firm	Firm has submitted their reply vide dairy No. 23364 dated 18-08-2022 along with form -5 dully signed by QC and Production In charge. Firm has also submitted BP specifications as finished good specification. Firm has also submitted copy DML renewal inspection conducted on 02-06-2022 which stated that the pane; unanimously recommended the approval of DML by way of formulation to M/s Reliance Pharma, plot No.8, street No. s-8, RCCI, Industrial Estate, Rawat with following sections 1- Tablet (General) 2-Capsule (General) 3-Ointment/Cream (General) 4-Gel (General)	
	Remarks of Evaluator	Firm has not submitted preregistration variation fee challan.	
	Decision: Approved with BP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021		
88.	Name and address of manufacturer/ Applicant	Reliance Pharma, Plot No.08, street No. S-8, RCCI Industrial Estate, Rawat, Islamabad.	
	Brand Name + Dosage Form + Strength	SULI-RIDE Tablet 100 mg	
	Composition	Each Tablet Contains: Amisulpride …….100 mg	
	Diary No. Date of R & I & fee	Dy. No 12513 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.	
	Pharmacological Group	Anti-psychotics	
	Type of Form	Form-5	
	Finished product Specification	BP specification	
	Pack size & Demanded Price	10’s, As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Amisulpride 100 mg Tablets, MHRA Approved.	
	Me-too status	Amilia 100mg Tablet, Evolution Pharma, Reg.No.101612.	
	GMP status	GMP status/report within last 3 years not provided	
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Finished Product specification not provided. • All the submitted Form-5 Annexures are without any signature/stamp on plain paper. • GMP inspection report conducted within last 3 years is not provided. • Preregistration variation fee challan.	

	Previous decision of 317th meeting: Deferred for following Shortcomings; 1. Finished Product specification not provided. 2. All the submitted Form-5 Annexures are without any signature/stamp on plain paper. 3. GMP inspection report conducted within last 3 years is not provided. 4. Preregistration variation fee challan.	
	Reply of Firm	Firm has submitted their reply vide dairy No. 23365 dated 18-08-2022 along with form -5 dully signed by QC and Production In charge. Firm has also submitted BP specifications as finished good specification. Firm has also submitted copy DML renewal inspection conducted on 02-06-2022 which stated that the pane; unanimously recommended the approval of DML by way of formulation to M/s Reliance Pharma, plot No.8, street No. s-8, RCCI, Industrial Estate, Rawat with following sections 1- Tablet (General) 2-Capsule (General) 3-Ointment/Cream (General) 4-Gel (General)
	Remarks of Evaluator	Firm has not submitted preregistration variation fee challan.
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
89.	Name and address of manufacturer/ Applicant	Reliance Pharma, Plot No.08, street No. S-8, RCCI Industrial Estate, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	SULI-RIDE Tablet 50 mg
	Composition	Each Tablet Contains: Amisulpride …….50 mg
	Diary No. Date of R & I & fee	Dy. No 12512 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Anti-psychotics
	Type of Form	Form-5
	Finished product Specification	BP specification
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Amisulpride 50mg Tablets by M/s Accord-UK Ltd (MHRA Approved)
	Me-too status	Solium-50 Tablets by M/s Genome Pharmaceuticals (Pvt,) Ltd (Reg#064017)
	GMP status	GMP status/report within last 3 years not provided
	Remarks of the Evaluator	Deficiency letter was issued to firm and asked to provide: • Finished Product specification not provided. • All the submitted Form-5 Annexures are without any signature/stamp on plain paper. • GMP inspection report conducted within last 3 years is not provided. • Preregistration variation fee challan.
	Previous decision of 317th meeting: Deferred for following Shortcomings; 1. Finished Product specification not provided. 2. All the submitted Form-5 Annexures are without any signature/stamp on plain paper.	

	3. GMP inspection report conducted within last 3 years is not provided. 4. Preregistration variation fee challan.	
	Reply of Firm	Firm has submitted their reply vide dairy No. 23365 dated 18-08-2022 along with form -5 dully signed by QC and Production In charge. Firm has also submitted BP specifications as finished good specification. Firm has also submitted copy DML renewal inspection conducted on 02-06-2022 which stated that the pane; unanimously recommended the approval of DML by way of formulation to M/s Reliance Pharma, plot No.8, street No. s-8, RCCI, Industrial Estate, Rawat with following sections 1- Tablet (General)` 2-Capsule (General) 3-Ointment/Cream (General) 4-Gel (General)
	Remarks of Evaluator	Firm has not submitted preregistration variation fee challan.
	Decision: Approved with USP specification. The firm shall submit preregistration variation fee of 7500/= as per SRO.No. F.7-11/2012- B&A/DRAP dated 13-07-2021	
90.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	D-LAN Capsule 30 mg
	Composition	Each Capsule Contains: Dexlansoprazole dual delayed released pellets (enteric coated) equivalent to Dexlansoprazole ……. …...30 mg
	Diary No. Date of R & I & fee	Dy. No 11998 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	30's, as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Delayed release Dexlansoprazole capsule 30 mg
	Me-too status	Razodex Capsule 30 mg by M/s Getz Pharma. (Reg.#086976)
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	• GMP inspection report within last 3 years is required. • Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. • Complete method of manufacturing is required. • Stability study data is required as per the guidelines approved in 293RD meeting of Registration Board
	Previous decision of 317th meeting: Deferred for following shortcomings; **1.** GMP inspection report within last 3 years is required. **2.** Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. **3.** Complete method of manufacturing is required. **4.** Stability study data is required as per the guidelines approved in 293RD meeting of Registration Board.	
	Reply of Firm	• Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form-5, dully signed and stamped and manufacturing method. Firm has also submitted summary of stability study data of finished product conducted for one batch (00) Mfg. date Feb 2019 at 30°C ±2 and 65 % (±5 %) for 24 months. • Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID ,Khi

		concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future.
	Remarks of Evaluator	• Firm has not submitted stability study data as per guidelines approved in 293rd meeting of DRB. • Firm has not declared source of pellets along with stability study data of 3 batches of Pellets, COAs and GMP of source of pellets, (in case of foreign Source, fee for source approval is also required). • Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. • Pre-registration variation fee challan is not provided.
	Decision: Deferred for following short comings: • **Firm has not submitted stability study data as per guidelines approved in 293rd meeting of DRB.** • **Firm has not declared source of pellets along with stability study data of 3 batches of Pellets, COAs and GMP of source of pellets, (in case of foreign Source, fee for source approval is also required).** • **Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** • **Pre-registration variation fee challan is not provided.**	
91.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	D-LAN Capsule 60 mg
	Composition	Each Capsule Contains: Dexlansoprazole dual delayed released pellets (enteric coated) equivalent to Dexlansoprazole ……. …...60 mg
	Diary No. Date of R & I & fee	Dy. No 11999 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	30's, as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Delayed release Dexlansoprazole capsule 60 mg
	Me-too status	Razodex 60mg Capsule by M/s Getz Pharma.
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	• GMP inspection report within last 3 years is required. • Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. • Complete method of manufacturing is required. • Stability study data is required as per the guidelines approved in 293RD meeting of Registration Board
	Previous decision of 317th meeting: Deferred for following shortcomings; **1.** GMP inspection report within last 3 years is required. **2.** Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. **3.** Complete method of manufacturing is required. **4.** Stability study data is required as per the guidelines approved in 293RD meeting of Registration Board.	
	Reply of Firm	• Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form-5, dully signed and stamped and manufacturing method. Firm has also submitted summary of stability study data of finished product conducted for one batch (001(1)) Mfg. date Feb 2019 at 30°C ±2 and 65 % (±5 %) for 24 months.

		• Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID ,Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future.
	Remarks of Evaluator	• Firm has not submitted stability study data as per guidelines approved in 293rd meeting of DRB. • Firm has not declared source of pellets along with stability study data of 3 batches of Pellets, COAs and GMP of source of pellets, (in case of foreign Source, fee for source approval is also required). • Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. • Pre-registration variation fee challan is not provided.
	Decision: Deferred for following short comings: • **Firm has not submitted stability study data as per guidelines approved in 293rd meeting of DRB.** • **Firm has not declared source of pellets along with stability study data of 3 batches of Pellets, COAs and GMP of source of pellets, (in case of foreign Source, fee for source approval is also required).** • **Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** • **Pre-registration variation fee challan is not provided.**	
92.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	Macopime Injection 1 G (I.V/I.M)
	Composition	Each vial Contain: Cefepime Hcl (with Sterile L-Arginine) eq.to Cefepime…….. 1G
	Diary No. Date of R & I & fee	Dy. No 11997 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	U.S.P specification
	Pack size & Demanded Price	1's Glass Vial (USP type II), as per SRO
	Approval status of product in Reference Regulatory Authorities	Cefipime hydrochloride 1gm Injection M/s Hospira, Inc. (USFDA approved)
	Me-too status	Nuxipim 1gm Injection by M/s Bosch, Reg. No. 44357
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	• GMP inspection report within last 3 years is required. • Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. • Complete method of manufacturing is required. • Section approval letter of Dry Powder Injection (cephalosporin) is required.
	Previous decision of 317th meeting: Deferred for following shortcomings; **1.** GMP inspection report within last 3 years is required. **2.** Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. **3.** Complete method of manufacturing is required. **4.** Section approval letter of Dry Powder Injection (Cephalosporin) from CLB is required**.**	
	Reply of Firm	• Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form -5 dully signed and stamped and manufacturing method. Firm has also mentioned Combo pack with Diluent "Each ampoule of solvent Contain: Sterile water for Injection (B.P) ……10 ml

		• Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID, Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future. • Firm has submitted Lay out plan approval letter of Cephalosporin section.
	Remarks of Evaluator	• Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. • Pre-registration variation fee challan is not provided. • Section approval letter of Cephalosporin from CLB is not provided.
	Decision: Deferred for following shortcomings: • **Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** • **Pre-registration variation fee challan is not provided.** • **Section approval letter from CLB is not provided**	
93.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	Macopime Injection 500 Mg (I.V/I.M)
	Composition	Each vial Contain: Cefepime Hcl (with Sterile L-Arginine) eq.to Cefipime…….. 500 Mg
	Diary No. Date of R & I & fee	Dy. No 11996 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	U.S.P specification
	Pack size & Demanded Price	1's Glass Vial (USP type II), as per SRO
	Approval status of product in Reference Regulatory Authorities	Cefipime hydrochloride 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too status	Nuxipim 500mg Injection by M/s Bosch, Reg. No. 44356
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	• GMP inspection report within last 3 years is required. • Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. • Complete method of manufacturing is required. • Section approval letter of Dry Powder Injection (cephalosporin) is required.
	Previous decision of 317th meeting: Deferred for following shortcomings; **1.** GMP inspection report within last 3 years is required. **2.** Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. **3.** Complete method of manufacturing is required. **4.** Section approval letter of Dry Powder Injection (Cephalosporin) from CLB is required.	
	Reply of Firm	• Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form -5 dully signed and stamped and manufacturing method. Firm has also mentioned Combo pack with Diluent "Each ampoule of solvent Contain: Sterile water for Injection (B.P) ……10 ml • Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID, Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future.

		• Firm has submitted Lay out plan approval letter of Cephalosporin section.
	Remarks of Evaluator	• Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. • Pre-registration variation fee challan is not provided. • Section approval letter of Cephalosporin from CLB is not provided.
	Decision: Deferred for following shortcomings: • **Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** • **Pre-registration variation fee challan is not provided.** • **Section approval letter from CLB is not provided**	
94.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	Macopime Injection 250 Mg (I.V/I.M)
	Composition	Each vial Contain: Cefepime Hcl (with Sterile L-Arginine) eq.to Cefipime…….. 250 Mg
	Diary No. Date of R & I & fee	Dy. No 11995 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	U.S.P specification
	Pack size & Demanded Price	1's Glass Vial (USP type II), as per SRO
	Approval status of product in Reference Regulatory Authorities	Approval status of product in Reference Regulatory Authorities not confirmed.
	Me-too status	
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	• GMP inspection report within last 3 years is required. • Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. • Complete method of manufacturing is required. • Section approval letter of Dry Powder Injection (cephalosporin) is required. • Approval status of product in Reference Regulatory Authorities not confirmed.
	Decision: Deferred for following shortcomings; **1.** GMP inspection report within last 3 years is required. **2.** Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. **3.** Complete method of manufacturing is required. **4.** Section approval letter of Dry Powder Injection (Cephalosporin) from CLB is required. **5.** Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Reply of Firm	• Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form -5 dully signed and stamped and manufacturing method. Firm has also mentioned Combo pack with Diluent "Each ampoule of solvent Contain: Sterile water for Injection (B.P) ……10 ml • Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID, Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future.

		• Firm has submitted Lay out plan approval letter of Cephalosporin section.
	Remarks of the Evaluator	• Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. • Pre-registration variation fee challan is not provided. • Section approval letter of Cephalosporin from CLB is not provided. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting and me too/generic product registered in Pakistan is not provided.
	Decision: Deferred for following shortcomings: • **Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** • **Pre-registration variation fee challan is not provided.** • **Section approval letter from CLB is not provided**	
95.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	ACIZOB Injection 4.5 G
	Composition	Each 4.5 G vial Contain: Piperacillin Sodium Eq to Piperacillin……...4 G Tazobactam Sodium Eq to Tazobactam……0.5 G
	Diary No. Date of R & I & fee	Dy. No 11994 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	U.S.P specification
	Pack size & Demanded Price	1's Glass Vial (USP type II), as per SRO
	Approval status of product in Reference Regulatory Authorities	Zosyn Injection USFDA Approved.
	Me-too status	Tacip Injection by Macter International (Reg#086976)
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	• GMP inspection report within last 3 years is required. • Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. • Complete method of manufacturing is required. • Section approval letter of Dry Powder Injection (cephalosporin) is required.
	Decision: Deferred for following shortcomings; **1.** GMP inspection report within last 3 years is required. **2.** Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. **3.** Complete method of manufacturing is required. **4.** Section approval letter of Dry Powder Injection (Penicillin) from CLB is required.	
	Reply of Firm	• Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form -5 dully signed and stamped and manufacturing method. Firm has also mentioned Combo pack with Diluent "Each ampoule of solvent Contain: Sterile water for Injection (B.P) ……10 ml • Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID, Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future.

		• Firm has submitted Lay out plan approval letter of Cephalosporin section.
	Remarks of the Evaluator	• Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5. • Pre-registration variation fee challan is not provided. • Section approval letter from CLB is not provided.
	Decision: Deferred for following shortcomings: • **Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** • **Pre-registration variation fee challan is not provided.** • **Section approval letter from CLB is not provided**	
96.	Name and address of manufacturer/ Applicant	Macquin's International, F-2/H., P.T.C Industrial Complex,S.I.T.E,Karachi.
	Brand Name + Dosa5ge Form + Strength	ACIZOB Injection 2.25 G
	Composition	Each 2.25 G vial Contain: Piperacillin Sodium Eq to Piperacillin……...2 G Tazobactam Sodium Eq to Tazobactam……0.25 G
	Diary No. Date of R & I & fee	Dy. No 11993 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	U.S.P specification
	Pack size & Demanded Price	1's Glass Vial (USP type II), as per SRO
	Approval status of product in Reference Regulatory Authorities	Zosyn Injection USFDA Approved.
	Me-too status	Tacip Injection by Macter International (Reg#086976)
	GMP status	Firm has not provided GMP within last 3 years.
	Remarks of the Evaluator	• GMP inspection report within last 3 years is required. • Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan. • Complete method of manufacturing is required. • Section approval letter of Dry Powder Injection (cephalosporin) is required.
	Decision: Deferred for following shortcomings; **1. GMP inspection report within last 3 years is required.** **2. Form-5 as per prescribed format of Drug Registering, Licensing & advertising is required along with preregistration fee challan.** **3. Complete method of manufacturing is required.** **4. Section approval letter of Dry Powder Injection (Penicillin) From CLB is required.**	
	Reply of Firm	• Firm has submitted reply vide dairy No. 23931 dated 24-08-2022 along with checklist of form -5 dully signed and stamped and manufacturing method. Firm has also mentioned Combo pack with Diluent "Each ampoule of solvent Contain: Sterile water for Injection (B.P) ……10 ml • Firm has also submitted copy of GMP inspection conducted on 24-02-2022 conducted by FID, Khi concluded that firm is operating at satisfactory level of GMP compliance with positive intention of firm for further improvement in future. • Firm has submitted Lay out plan approval letter of Cephalosporin section.
	Remarks of the Evaluator	• Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing &

		advertising rules 1976 along with undertaking at the end of form-5. • Pre-registration variation fee challan is not provided. • Section approval letter from CLB is not provided.
	Decision: Deferred for following shortcomings: • **Firm has not submitted form -5 as per prescribed format of form-5 as per Drug Registering, Licensing & advertising rules 1976 along with undertaking at the end of form-5.** • **Pre-registration variation fee challan is not provided.** • **Section approval letter from CLB is not provided**	
97.	Name and address of manufacturer/ Applicant	M/s A.H. Pharmaceuticals (Pvt) Ltd, 865/A. S.I.T.E, Sargodha Road, Faislabad
	Brand Name + Dosa5ge Form + Strength	Keachlor Syrup
	Composition	Each 5ml Contains: Chlorpheniramine maleate ……..2mg
	Diary No. Date of R & I & fee	Dy.No. 5731 dated 16-02-2018 Rs. 20,000/-
	Pharmacological Group	Anti-allergic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	could not be confirmed
	Me-too status	Staiton Syrup of Standard Drug Company, Hyderabad.
	GMP status	GMP Inspection conducted on 04-07-2017 recommended renewal of DML by the way of formulation.
	Remarks of the Evaluator	Evidence of reference Product in plastic container is required.
	Previous Decision of 290th meeting	Registration Board in its 290th meeting decided as follow: • For evidence of approval of applied formulation in HDPE Bottle in reference agencies. • Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) along with registration number, brand name and name of firm is required.
	Evaluation By PEC	Applicant has submitted the following: • We will use highly resistant amber glass bottles along with aluminum seal cap. • Evidence of Me too: • Evidence of International availability:
	Previous Decision of 292nd meeting	Deferred for the following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.\ • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Reply of firm	Firm has submitted reply vide Dairy No. 2097 PEC DRAP dated 14-09-2022 and refereed to • Reg 068446 Colen Syrup by Alliance Pharmaceuticals (Pvt) Ltd, 112-A, Hayatabad Industrial Estate Jamrud Road, Peshawar. • Piriton Syrup,MHRA Approved (150 ml amber glass and plastic bottle)
	Remarks of evaluator	• Current GMP status of firm • Innovator Specification • Reference product pack size is 150 ml whereas applied pack size is 120 ml.

	Decision: Approved with innovator specification. The firm shall submit valid GMP certificate/inspection before issuance of registration letter.The firm shall submit preregistration variation fee of 7500/= for revision of finished product specification as per SRO.No. F.7-11/2012-B&A/DRAP dated 13-07-2021

Agenda of Evaluator PEC-XII

98.	Name, address of Applicant / Marketing Authorization Holder	M/s StandPharm Pakistan (Pvt) Ltd, 20 Km, Ferozpur Road, Lahore
	Name, address of Manufacturing site.	M/s StandPharm Pakistan (Pvt) Ltd, 20 Km, Ferozpur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28327 dated 14/10/2021
	Details of fee submitted	PKR 30,000/-: dated 28/09/2021
	The proposed proprietary name / brand name	Riomed DS Suspension 250mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml (when reconstituted) contains: Clarithromycin (as taste masked granules 27.5%) ……..... 250mg
	Pharmaceutical form of applied drug	White to off-white granular powder packed in Plastic Bottle (HDPE)
	Pharmacotherapeutic Group of (API)	Macrolide antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (60 ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 250mg/5ml granules for oral suspension by Abbott Laboratories Limited (UK) MHRA Approved.
	For generic drugs (me-too status)	Klaricid DS Suspension by Abbott Laboratories (Pakistan) Ltd. Reg. No. 076148
	GMP status of the Finished product manufacturer	StandPharm Pakistan (Pvt) Ltd: DML renewal inspection report conducted on 18-02-2020 recommending renewal of DML.
	Name and address of API manufacturer.	M/s Surge Laboratories (Pvt) Ltd. 10-KM, Faisalabad Road Bikhi, District Sheikhupura – Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Clarithromycin for oral suspension is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: CTM-AB-001J, CTM-AB-002J, CTM-AB-003J
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation, control of excipients, control of drug product. Specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against the Klaricid DS Suspension by Abbott Laboratories (Pakistan) Ltd. The results of all the tests of both products falls within the specifications and are comparable.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity, repeatability, linearity.

STABILITY STUDY DATA

Manufacturer of API	M/s Surge Laboratories (Pvt) Ltd. 10th KM, Faisalabad Road Bikhi, District Sheikhupura – Pakistan.		
API Lot No.	CTM-1-566		
Description of Pack (Container closure system)	Plastic Bottle (HDPE) 100ml with spoon, leaflet and unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 26 weeks Accelerated: 26 weeks		
Frequency	Accelerated: 0,1,2,3,4,6,8,12,16,20,24, 26 weeks Real Time: 0,1,2,3,4,6,8,12,16,20,24, 26 weeks		
Batch No.	TRLRS-001	TRLRS-002	TRLRS-003
Batch Size	200 vials	200 vials	200 vials
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	03-05-2019	07-05-2019	08-05-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Neon 2g IV Injection approved in 317th meeting of Registration Board (16-17 May 2022).

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 182/2019-DRAP (AD-823166-158) dated 04-07-2019 issued by DRAP, Lahore. DML No. 000649 renewed w.e.f. 12-12-2018.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice No.19010534-SG dated 29-01-2019 Batch # CTM-1-5-66 specifying local purchase of 50 kg from surge laboratories.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

i. GMP inspection report/ GMP certificate issued within the last three years is not submitted. However, panel inspection report for renewal of DML conducted on 18-02-2020 is submitted.
ii. The firm has used batch size of only 200 Bottles in stability studies without any justification.
iii. Frequency of testing is different (0,1,2,3,4,6,8,12,16,20,24, 26 weeks) from standard frequency (0,3,6 months) in stability studies.

Decision: Approved.

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

Agenda of AD PE&R (Sarfraz Nawaz)

Registration applications for local manufacturing of (veterinary) drugs:

a) New/Additional Section(s)

M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar Industrial Estate, Haripur:

The Central Licensing Board in its 286th meeting held on 11th May, 2022 has considered and approved the following six (06) additional sections in the name of M/s M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar Industrial Estate, Haripur by way of Formulation under Drug Manufacturing License No. 000298 (Formulation):-

		Block-B	
S#	**Name of Section**	**S#**	**Name of Section**
1.	Oral Powder-II (General-Veterinary)- **Additional**	2.	Oral Powder Section-III (General-Veterinary)- **Additional**
3.	Oral Liquid-II (General-Veterinary)- **Additional**	4.	Steroid Injection (Veterinary)- **Additional**
5.	Oral Bolus-II (General-Veterinary)- **Additional**	6.	Liquid Injection Section (General-Veterinary)- **Additional**

Following applications have been submitted by the firm against above sections

Liquid Injection Section (General-Veterinary) (35 Products / 5 Molecules)		
99.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar Industrial Estate, Haripur.

	Brand Name +Dosage Form + Strength	F-MEC 1% INJECTION
	Composition	Each 100ml contains: Ivermectin ……1gm
	Diary No. Date of R& I & fee	Dy No.22316-R & I dated 05-08-2022, Fee Rs: 30,000/ Deposit slip No. 80647069899
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Iverexcel 10 injection (10ml) Each ml contains: - Ivermectin……10mg (Mediexcel pharmaceuticals, Islamabad. Reg # 106682
	Remarks of the Evaluator	Label claim has to be standardized as follow: Each ml contains: Ivermectin BP……10mg
	Decision: Approved	
100.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-MEC 1% INJECTION
	Composition	Each 100ml contains Ivermectin BP……1g
	Diary No. Date of R& I & fee	Dy No.22317-R & I dated 05-08-2022, Fee Rs: 30,000/ Deposit slip No. 6291225028
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Iverexcel 10 injection Each ml contains: - Ivermectin……10mg (Mediexcel pharmaceuticals, Islamabad. Reg # 106683
	Remarks of the Evaluator	Label claim has to be standardized as follow: Each ml contains: Ivermectin BP……10mg
	Decision: Approved	
101.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-MEC 1% INJECTION
	Composition	Each 100ml contains Ivermectin BP……1g
	Diary No. Date of R& I & fee	Dy No.22318-R&I dated 05-08-2022, Fee Rs: 30,000/ Deposit slip No. 0523623026
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	IVORON INJECTION (100ml) Each ml contains: - Ivermectin……10mg M/s. D-Maarson Pharmaceuticals, Islamabad. Reg # 102148
	Remarks of the Evaluator	Label claim has to be standardized as follow: Each ml contains: Ivermectin BP……10mg
	Decision: Approved	

102.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-MEC 1% INJECTION
	Composition	Each 100ml contains Ivermectin BP……1g
	Diary No. Date of R& I & fee	Dy No.22319-R&I dated 05-08-2022, Fee Rs: 30,000/ Deposit slip No. 85999743517
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	500ml/Decontrolled
	Me-too status (with strength and dosage form)	EVEREST 1% INJECTION (500ml) Each ml contains: - Ivermectin……10mg M/s. Vetz Pharmaceuticals (Pvt.) Ltd. Kotri Sindh. Reg # 102011
	Remarks of the Evaluator	Label claim has to be standardized as follow: Each ml contains: Ivermectin BP……10mg
	Decision: Approved	
103.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar. Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-MEC 2% INJECTION
	Composition	Each ml contains Ivermectin ……20mg
	Diary No. Date of R& I & fee	Dy No. 22320-R&I dated 05.08.2022. Fee Rs: 30,000/- deposit slip No. 7749889386
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Iverexcel 20 Injection (10ml) of M/s. Mediexcel Pharmaceuticals, Islamabad.Reg # 106684
	Decision: Approved	
104.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar. Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-MEC 2% INJECTION (50ml)
	Composition	Each ml contains (BP) Ivermectin BP……20mg
	Diary No. Date of R& I & fee	Dy No. 22321-R&I dated 05.08.2022. Fee Rs: 30,000/- deposit slip No. 510893371311
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Iverexcel 20 Injection (50ml) of M/s. Mediexcel Pharmaceuticals, Islamabad.Reg # 106685
	Decision: Approved	
105.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar. Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-MEC 2% INJECTION
	Composition	Each ml contains Ivermectin ……20mg

	Diary No. Date of R& I & fee	Dy No. 22322-R&I dated 05.08.2022. Fee Rs: 30,000/- deposit slip No. 0324166927
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	SELMEC INJECTION (10ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals, Lahore. Reg # 071087
	Decision: Approved	
106.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar. Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-MEC 3.15% INJECTION
	Composition	Each ml contains Ivermectin BP……3.15%
	Diary No. Date of R& I & fee	Dy No. 22323-R&I dated 05.08.2022. Fee Rs: 30,000/- deposit slip No. 4754034776
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	MECTI DS INJECTION (50ML) Each ml contains: - Ivermectin……...3.15% of M/s International Pharma labs. Lahore. Reg. # 094428
	Decision: Approved	
107.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar. Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-MEC 3.15% INJECTION
	Composition	Each ml contains Ivermectin ……3.15%
	Diary No. Date of R& I & fee	Dy No. 22324-R&I dated 05.08.2022. Fee Rs: 30,000/- deposit slip No. 1610927914
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	ELVOMEC STAR INJECTION 3.15% (10ml, 50ml, 100ml) Each ml contains: - Ivermectin……...3.15% of M/s Elko organization (pvt) ltd., Karachi. Reg. # 063728
	Decision: Approved	
108.	**Name and address of manufacturer / Applicant**	M/s Farm Aid Group, Plot No. 3/2, Phase I & II, Hattar. Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	FAG OX 5% INJECTION
	Composition	Each ml contains: Oxytetracycline HCl……. 50mg
	Diary No. Date of R& I & fee	Dy. No.22325 dated 05.08.2022, Fee Rs: 30,000/- deposit slip No.7415709858
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Terrarok-M 50 Parenteral Solution (10ml, 50ml, 100ml) f M/s Manhattan Pharma, Karachi. Reg. No. 074043

	Remarks of the Evaluator	
	Decision: Approved	
109.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAG OX 5% INJECTION**
	Composition	Each ML Contains Oxytetracycline Hcl……..50mg
	Diary No. Date of R& I & fee	Dy No.22326: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Terrarok-M 50 Parenteral Solution (Manhattan Pharma) Reg # 074043
	Remarks of the Evaluator	
	Decision: Approved	
110.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAG OX 10% INJECTION**
	Composition	Each ml Contains Oxytetracycline Hcl……..100mg
	Diary No. Date of R& I & fee	Dy No.22327: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	B.G OXY 100 INJECTION (Bio Gen Pharma) Reg # 075615
	Remarks of the Evaluator	
	Decision: Approved	
111.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAG OX 10% INJECTION**
	Composition	Each ML Contains Oxytetracycline Hcl……..100mg
	Diary No. Date of R& I & fee	Dy No.22328: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	B.G OXY 100 INJECTION (Bio Gen Pharma) Reg # 075615
	Remarks of the Evaluator	
	Decision: Approved	
112.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAG OX 20% INJECTION**
	Composition	Each ML Contains: Oxytetracycline Hcl……..200mg
	Diary No. Date of R& I & fee	Dy No.22329: 05.08.2022 PKR. 30,000/-; 04.08.2022

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Anaoxy-cp-Injection (M/S Cherrished) Reg # 043563
	Remarks of the Evaluator	
	Decision: Approved	
113.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAG OX 20% INJECTION**
	Composition	Each ML Contains Oxytetracycline HCl……..200mg
	Diary No. Date of R& I & fee	Dy No. 22330: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Anaoxy-cp-Injection (M/S Cherrished) Reg # 043563
	Remarks of the Evaluator	
	Decision: Approved	
114.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAG OX 30% INJECTION**
	Composition	Each ml Contains Oxytetracycline ....300mg (as HCL)
	Diary No. Date of R& I & fee	Dy No.22331: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	EL-Cycline D.S.Injection (M/S Elko Organisation) Reg # 052310
	Remarks of the Evaluator	Apply as per reference and as per claim i.e. 30%
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
115.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F LOX 5 INJECTION**
	Composition	Each ml Contains Meloxicam ……..5mg
	Diary No. Date of R& I & fee	Dy No.22332: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	NSAID, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Diclostar Super Injection (M/S Star Labs) Reg # 053957
	Remarks of the Evaluator	
	Decision: Approved	

116.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F LOX 5 INJECTION**
	Composition	Each ml Contains Meloxicam BP ……..5mg
	Diary No. Date of R& I & fee	Dy No.22333: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	NSAID, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Diclostar Super Injection (M/S Star Labs) Reg # 053957
	Remarks of the Evaluator	
	Decision: Approved	
117.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F LOX 7.5 INJECTION**
	Composition	Each ml Contains BP Meloxicam BP ……..7.5mg
	Diary No. Date of R& I & fee	Dy No.22334: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	NSAID, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Camilox Injection (M/S Sell morePharma) Reg # 071089
	Remarks of the Evaluator	
	Decision: Approved	
118.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F LOX 7.5 INJECTION**
	Composition	Each ml Contains Meloxicam BP ……..7.5mg
	Diary No. Date of R& I & fee	Dy No.22335: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	NSAID, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Camilox Injection (M/S Sell more Pharma) Reg # 071089
	Remarks of the Evaluator	
	Decision: Approved	
119.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F LOX 10 INJECTION**
	Composition	Each ML Contains Meloxicam BP ……..10mg
	Diary No. Date of R& I & fee	Dy No.22336: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	NSAID, Anti-inflammatory
	Type of Form	Form 5

	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-10 Injection (M/S Sell more Pharma) Reg # 049643
	Remarks of the Evaluator	
	Decision: Approved	
120.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F LOX 10 INJECTION**
	Composition	Each ml Contains Meloxicam BP ……..10mg
	Diary No. Date of R& I & fee	Dy No.22337: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	NSAID, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-10 Injection (M/S Sell more Pharma) Reg # 049643
	Remarks of the Evaluator	
	Decision: Approved	
121.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F LOX 20 INJECTION**
	Composition	Each ml Contains Meloxicam ……..20mg
	Diary No. Date of R& I & fee	Dy. No.22338: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	NSAID, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-20 Injection (M/S Sell more Pharma) Reg # 057007
	Remarks of the Evaluator	
	Decision: Approved	
122.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F LOX 20 INJECTION**
	Composition	Each ml Contains Meloxicam ……..20mg
	Diary No. Date of R& I & fee	Dy No.22339: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	NSAID, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-20 Injection (M/S Sell more Pharma) Reg # 057007
	Remarks of the Evaluator	
	Decision: Approved	
123.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAGOCIN 10% INJECTION**

	Composition	Each 100ML Contains Enrofloxacin BP ……..10g
	Diary No. Date of R& I & fee	Dy No. 22341: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	DR-Flox -10 Injection (M/S International Pharma) Reg # 053980
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
124.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAGOCIN 10% INJECTION**
	Composition	Each 100ML Contains: Enrofloxacin BP ……..10g
	Diary No. Date of R& I & fee	Dy No.223432/ 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	DR-Flox -10 Injection (M/S International Pharma) Reg # 053980
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
125.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAGOCIN 10% INJECTION**
	Composition	Each 100ML Contains: Enrofloxacin BP ……..10g
	Diary No. Date of R& I & fee	Dy No.22340: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	DR-Flox -10 Injection (M/S International Pharma) Reg # 053980
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
126.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAGOCIN 20% INJECTION**
	Composition	Each 100ML Contains Enrofloxacin BP ……..20g
	Diary No. Date of R& I & fee	Dy No.22343: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled

	Me-too status (with strength and dosage form)	Quinosel Injection (M/S Sell More Pharma) Reg # 057009
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
127.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAGOCIN 20% INJECTION**
	Composition	Each 100ML Contains Enrofloxacin BP ……..20g
	Diary No. Date of R& I & fee	Dy No. 22344: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Quinosel Injection (M/S Sell More Pharma) Reg # 057009
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
128.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FAGOCIN 20% INJECTION**
	Composition	Each 100ML Contains Enrofloxacin BP ……..20g
	Diary No. Date of R& I & fee	Dy No.22345: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Enrock Injection (M/S International Pharma) Reg # 053983
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
129.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FT GEN 510 INJECTION**
	Composition	Each ML Contains: Gentamicin Sulphate ……..50mg Tylosin Tartrate……100mg
	Diary No. Date of R& I & fee	Dy No.22346: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Tygent Injection (M/S Sell More Pharma) Reg # 049636
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
130.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan

	Brand Name +Dosage Form + Strength	**FT GEN 510 INJECTION**
	Composition	Each ML Contains: Gentamicin Sulphate BP ……..50mg Tylosin Tartrate BP……100mg
	Diary No. Date of R& I & fee	Dy No.22347: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Tygent Injection (M/S Sell More Pharma) Reg # 049636
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
131.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FT GEN 510 INJECTION**
	Composition	Each ml Contains Gentamicin Sulphate BP ……..50mg Tylosin Tartrate BP……100mg
	Diary No. Date of R& I & fee	Dy No.22348: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Gentawal Injection (M/s Nawal Pharma) Reg # 074088
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
132.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FT GEN 150 INJECTION**
	Composition	Each ML Contains Gentamicin Sulphate BP ……..100mg Tylosin Tartrate BP……50mg
	Diary No. Date of R& I & fee	Dy No.22349: 05.08.2022 PKR. 30,000/-; 04.08.2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	BG Genta Injection (M/S Bio Gen Pharma) Reg # 075624
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
133.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**FT GEN 150 INJECTION**
	Composition	Each ML Contains Gentamicin Sulphate BP ……..100mg Tylosin Tartrate BP……50mg
	Diary No. Date of R& I & fee	Dy No.22350: 05.08.2022 PKR. 30,000/-; 04.08.2022

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	BG Genta Injection (M/S Bio Gen Pharma) Reg # 075624
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	

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134.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**PEDISON 10 INJECTION**
	Composition	Each ml contains:- Prednisolone Acetate……. 10mg
	Diary No. Date of R& I & fee	Dy No. 22279: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Acetosol DS Injection (M/S International Pharma) Reg # 099030
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
135.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**PEDISON 25 INJECTION**
	Composition	Each ml contains:- Prednisolone Acetate……. 25mg
	Diary No. Date of R& I & fee	Dy No.22280: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Predison Injection 2.5% (M/S Manhattan Pharma) Reg # 035091
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
136.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**PEDISON 25 INJECTION**
	Composition	Each ml contains:- Prednisolone Acetate……. 25mg
	Diary No. Date of R& I & fee	Dy No.22281: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications

	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Predison Injection 2.5% (M/S Manhattan Pharma) Reg # 035091
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
137.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F-Dex 1 INJECTION**
	Composition	Each ml contains:- Dexamethasone Sodium Phosphate……. 1mg
	Diary No. Date of R& I & fee	Dy No. 22282: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Dexamethasone 1mg/ml Injection 2.5% (M/S Venus Pharma) Reg # 031511
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
138.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase 1/11 HattarIndustrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F-Dex 2 INJECTION**
	Composition	Each 2ml contains:- Dexamethasone Sodium Phosphate Eq to 4mg Dexamethasone Base
	Diary No. Date of R& I & fee	Dy No.22283: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Dexamethasone Injection (M/S Elko Organisation) Reg # 017071
	Remarks of the Evaluator	
	Decision: Approved	
139.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F-Dex 2 INJECTION**
	Composition	Each 2ml contains: Dexamethasone Sodium Phosphate Eq to 4mg Dexamethasone Base
	Diary No. Date of R& I & fee	Dy No.22284: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications

	Pack size & Demanded Price	30ml/Decontrolled
	Me-too status (with strength and dosage form)	Dexamethasone Injection (M/S Elko Organisation) Reg # 017071
	Remarks of the Evaluator	
	Decision: Approved	
140.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F-Dex 2 INJECTION**
	Composition	Each 2ml contains:- Dexamethasone Sodium Phosphate Eq to 4mg Dexamethasone Base
	Diary No. Date of R& I & fee	Dy No.22285: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Dexamethasone Injection (M/S Elko Organisation) Reg # 017071
	Remarks of the Evaluator	
	Decision: Approved	
141.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F-Dex 4 INJECTION**
	Composition	Each ml contains:- Dexamethasone Sodium Phosphate…….4mg
	Diary No. Date of R& I & fee	Dy No.22286: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	B.G Dexameth Injection (M/S Bio Gen Pharma) Reg # 072646
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
142.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F-Dex 4 INJECTION**
	Composition	Each ml contains: Dexamethasone Sodium Phosphate…….4mg
	Diary No. Date of R& I & fee	Dy No.22287: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	30ml/Decontrolled
	Me-too status (with strength and dosage form)	B.G Dexameth Injection (M/S Bio Gen Pharma) Reg # 072646
	Remarks of the Evaluator	

	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
143.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F-Dex 4 INJECTION**
	Composition	Each ml contains:- Dexamethasone Sodium Phosphate…….4mg
	Diary No. Date of R& I & fee	Dy No. 22288: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	B.G Dexameth Injection (M/S Bio Gen Pharma) Reg # 072646
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
144.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F-Dex 5 INJECTION**
	Composition	Each ml contains:- Dexamethasone…….5mg
	Diary No. Date of R& I & fee	Dy No.22289: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Dexon-5 Injectable (M/S Avicenna Laboratories) Reg # 035006
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
145.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**F-Dex 5 INJECTION**
	Composition	Each ml contains:- Dexamethasone…….5mg
	Diary No. Date of R& I & fee	Dy No.22290: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Dexon-5 Injectable (M/S Avicenna Laboratories) Reg # 035006
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Approved with USP specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

146.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**DP INJECTION**
	Composition	Each ml contains:- Prednisolone (as Acetate)……7.5mg Dexamethasone(as sodium Phosphate)…….2.5mg
	Diary No. Date of R& I & fee	Dy No. 22291: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Duracort Injection(M/S My Labs Pharma) Reg # 073913
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
147.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**DP INJECTION**
	Composition	Each ml contains:- Prednisolone (As Acetate)……7.5mg Dexamethasone(As sodium Phosphate)…….2.5mg
	Diary No. Date of R& I & fee	Dy No. 22292 : 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Duracort Injection (M/S My Labs Pharma) Reg # 073913
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
148.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**DP INJECTION**
	Composition	Each ml contains:- Prednisolone (As Acetate)……7.5mg Dexamethasone(As sodium Phosphate)…….2.5mg
	Diary No. Date of R& I & fee	Dy No. 22293: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Duracort Injection (M/S My Labs Pharma) Reg # 073913
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
149.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**PCM 14 INJECTION**

	Composition	Each ml contains:- Prednisolone ……10mg Chlorpheniramine Maleate…….4mg
	Diary No. Date of R& I & fee	Dy No.22294: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Solomin Injection (M/S Sell More Pharma) Reg # 049642
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
150.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**PCM 14 INJECTION**
	Composition	Each ml contains:- Prednisolone ……10mg Chlorpheniramine Maleate…….4mg
	Diary No. Date of R& I & fee	Dy No.22295: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Solomin Injection (M/S Sell More Pharma) Reg # 049642
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
151.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**PCM 14 INJECTION**
	Composition	Each ml contains:- Prednisolone ……10mg Chlorpheniramine Maleate…….4mg
	Diary No. Date of R& I & fee	Dy No.22296: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Solomin Injection (M/S Sell More Pharma) Reg # 049642
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
152.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**PCM 35 INJECTION**
	Composition	Each ml contains: - Prednisolone Acetate……25mg Chlorpheniramine Maleate…….10mg
	Diary No. Date of R& I & fee	Dy No.22297: 05.08.2022 PKR. 30,000/-; 03.08.2022

	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Predmine Injection (M/S Cherished Pharma) Reg # 057084
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
153.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**PCM 35 INJECTION**
	Composition	Each ml contains:- Prednisolone Acetate……25mg Chlorpheniramine Maleate…….10mg
	Diary No. Date of R& I & fee	Dy No. 22298: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	20ml/Decontrolled
	Me-too status (with strength and dosage form)	Predmine Injection (M/S Cherished Pharma) Reg # 057084
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
154.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**Dexbro INJECTION**
	Composition	Each ml contains:- Colistine Sulphate……1250mg Tylosin Tartrate……10mg Bromhexine Hcl……100mg Dexamethasone……50mg
	Diary No. Date of R& I & fee	Dy No.22299: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Broncho-Dilator
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Colitylo Plus Injection (M/S Allina Combine) Reg # 052336
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
155.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**Dexbro INJECTION**
	Composition	Each ml contains:- Colistine Sulphate……1250mg Tylosin Tartrate……10mg Bromhexine Hcl……100mg Dexamethasone……50mg
	Diary No. Date of R& I & fee	Dy No.22300: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Broncho-Dilator
	Type of Form	Form 5

	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Colitylo Plus Injection (M/S Allina Combine) Reg # 052336
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
156.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**Dexbro INJECTION**
	Composition	Each ml contains:- Colistine Sulphate……1250mg Tylosin Tartrate……10mg Bromhexine Hcl……100mg Dexamethasone……50mg
	Diary No. Date of R& I & fee	Dy No. 22301: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Broncho-Dilator
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Colitylo Plus Injection (M/S Allina Combine) Reg # 052336
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
157.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**TADEX INJECTION**
	Composition	Each ml contains:- Oxytetracycline Hcl……150mg Dexamethasone Sodium Phosphate……0.5mg Tripelennamine Hcl…….10mg
	Diary No. Date of R& I & fee	Dy No.22302: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Decaline Injection(M/S Hilton Pharma) Reg # 028543
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
158.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**TADEX INJECTION**
	Composition	Each ml contains:- Oxytetracycline Hcl……150mg Dexamethasone Sodium Phosphate……0.5mg TripelennamineHcl…….10mg
	Diary No. Date of R& I & fee	Dy No. 22303: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled

	Me-too status (with strength and dosage form)	Decaline Injection (M/S Hilton Pharma) Reg # 028543
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
159.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**TADEX INJECTION**
	Composition	Each ml contains:- Oxytetracycline Hcl……150mg Dexamethasone Sodium Phosphate……0.5mg Tripelennamine Hcl…….10mg
	Diary No. Date of R& I & fee	Dy No.22304: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Decaline Injection (M/S Hilton Pharma) Reg # 028543
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
160.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**GENTO INJECTION**
	Composition	Each 100ml contains: - Tylosin Tartrate…….15gm Gentamycin Sulphate…….6gm Dexamethasone ……0.0265gm Chlorpheniramine…….0.750gm
	Diary No. Date of R& I & fee	Dy No.22305: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	GentaCombisone Injection(M/S LeadsPharma) Reg # 046696
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
161.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**GENTO INJECTION**
	Composition	Each 100ml contains:- Tylosin Tartrate…….15gm Gentamycin Sulphate…….6gm Dexamethasone ……0.0265gm Chlorpheniramine…….0.750gm
	Diary No. Date of R& I & fee	Dy No.22306: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	GentaCombisone Injection (M/S Leads Pharma) Reg # 046696

	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
162.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**GENTO INJECTION**
	Composition	Each 100ml contains:- Tylosin Tartrate…….15gm Gentamycin Sulphate…….6gm Dexamethasone ……0.0265gm Chlorpheniramine…….0.750gm
	Diary No. Date of R& I & fee	Dy No.22307: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	GentaCombisone Injection (M/S Leads Pharma) Reg # 046696
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
163.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**THIASOL INJECTION**
	Composition	Each ml contains:- Thiamphenicol……200mg Tylosin ……..…….57.5mg Prednisolone…..…….5mg
	Diary No. Date of R& I & fee	Dy No.22308: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Tylopen Injection (M/S Sellmore Agencies) Reg # 058815
	Remarks of the Evaluator	Apply for salt form as per reference
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
164.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**DEXTYL INJECTION (20ML)**
	Composition	Each ml contains:- Tylosin …….200mg Dexamethasone ……1mg
	Diary No. Date of R& I & fee	Dy No.22310: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	20ml/Decontrolled
	Me-too status (with strength and dosage form)	Tylovet Plus Injection (M/S Leads Pharma) Reg # 057055
	Remarks of the Evaluator	Apply for salt form as per reference
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	

165.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**DEXTYL INJECTION (10ML)**
	Composition	Each ml contains:- Tylosin …….200mg Dexamethasone ……1mg
	Diary No. Date of R& I & fee	Dy No.22309: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Tylovet Plus Injection (M/S Leads Pharma) Reg # 057055
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
166.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**KENA DEX INJECTION (100ML)**
	Composition	Each ml contains:- Kanamycin Sulphate……..50mg Colistine Sulphate……..100,000IU Neomycin Sulphate…….50mg Dexamethasone Sodium Phosphate……0.5mg
	Diary No. Date of R& I & fee	Dy No.22312: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	KonoDex Injection (M/S Allina Combine) Reg # 052347
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
167.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	**KENA DEX INJECTION (50ML)**
	Composition	Each ml contains:- Kanamycin Sulphate……..50mg Colistine Sulphate……..100,000IU Neomycin Sulphate…….50mg Dexamethasone Sodium Phosphate……0.5mg
	Diary No. Date of R& I & fee	Dy No.22311: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Kano Dex Injection (M/S Allina Combine) Reg # 052347
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	

Oral Powder Section -II (General Veterinary)-Additional		
2 Products / 2 Molecules		
168.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Fofo Forte Powder**
	Composition	Each 100gm Contains: - Fosfomycin Calcium…….....20gm Tylosin Tartrate……...10gm Fructose……...18gm Sodium Phosphate……...15gm Magnesium Phosphate…....10gm
	Diary No. Date of R& I & fee	Dy No.22752: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Antibiotic, Minerals
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Fosfotyl Powder (Leads Pharma) Reg # 078240
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
169.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Fofo Powder**
	Composition	Each 100gm Contains: - Calcium Fosfomycin…….....20gm Tylosin Tartrate…….....5gm Fructose 1,6 Diphosphate .....18gm Sodium Phosphate……...15gm Magnesium Phosphate…....10gm
	Diary No. Date of R& I & fee	Dy No. 22751: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Antibiotic, Minerals
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Fofact Powder (Univet Pharma) Reg # 075626
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	

Oral Powder Section -III (General Veterinary)-Additional		
8 Products / 7 Molecules		
170.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Fagoban Powder**
	Composition	Each 12 Gm Contains: - Neomycin Sulphate …….400mg Streptomycin Sulphate…… 400mg, Sulphaguanidine…….. 4gm Kaolin …… 4gm, Pectin…….. 400mg,

		Bismuch Subnitrate…… 2gm, Vit A Acetate…….. 80000 IU
	Diary No. Date of R& I & fee	Dy No.22739: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Antibiotic, Anti-diarrheals
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Diarroban Powder (Star Labs) Reg # 026438
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
171.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Fagofen 50% Powder**
	Composition	Each gm Contains:- Florfenicol C.P.V. 500mg.
	Diary No. Date of R& I & fee	Dy No. 22740: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Antibiotic,
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Naflor Powder (Nawan Labs) Reg # 049513
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
172.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Fimbo Powder**
	Composition	Each 100 Gm Contains : Potassium Citrate ----18 Gm Sodium Citrate ----12 Gm Vitamin B1------0.03 GM Vitamin B2-----0.015 GM Nictonamide -----0.32 Gm Menadione Bisulphate---- 0.115 Gm Vitamin C -----1.10 Gm
	Diary No. Date of R& I & fee	Dy No. 22741: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Multivitamins Minerals
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Bimbo-H W/S Powder (D-Haans Pharma) Reg # 102231
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
173.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**CS LINE Powder**

	Composition	Each Gm Contains:- Spiramycin Adipate 25mg. Chlortetracycline Hcl 75mg.
	Diary No. Date of R& I & fee	Dy No.22742: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Antibiotic,
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Spirachlor Powder (Sellmore Pharma) Reg # 049619
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
174.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F GEN Powder**
	Composition	Each Kg Contain Virginiamycin 400gm
	Diary No. Date of R& I & fee	Dy No. 22743: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Antibiotic,
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Vety-Grow Powder (Vety Care) Reg # 019939
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
175.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F GEST Powder**
	Composition	Each 1000gram Contains:- Propionic Acid Calcium..... 250gm Propionic Acid Sodium.....400gm Acetanilide.....……150gm Magnesium Oxide..... …125gm Iron Ii Sulphate…….....400mg Zinc Sulphate …….....100mg Magnesium Sulphate....200mg Copper Ulphate..……450mg Cobalt Sulphate...…. ….400mg Sodium Molybdate…… 100mg Sodium Chloride ……....20gm
	Diary No. Date of R& I & fee	Dy No.22744: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Minerals
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Anigest Powder (My Labs) Reg # 073906
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
176.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur

	Brand Name +Dosage Form + Strength	**F-Ben 400 Granules**
	Composition	Each Kg Contains:- Albendazole ….. 400gm
	Diary No. Date of R& I & fee	Dy No.22745: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Albak 400 Granules (Attabak Pharma) Reg # 049706
	Remarks of the Evaluator	
	Decision: Approved	
177.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F-Ben 200 Granules**
	Composition	Each Kg Contains:- Albendazole…… 200gm
	Diary No. Date of R& I & fee	Dy No.22753: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10g,20g,30g,50g,100g,500g,1kg,5kg
	Me-too status (with strength and dosage form)	Albak Granules (Attabak Pharma) Reg # 048164
	Remarks of the Evaluator	
	Decision: Approved	

Oral Bolus Section-II (General Veterinary) - Additional		
22 Products / 10 Molecules		
178.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Falbenda 200 Bolous**
	Composition	Each Bolus Contains:- Albendazole……. 200mg.
	Diary No. Date of R& I & fee	Dy No.22754 : 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10`s, 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Alben Par 200 Bolus (Grand Pharma) Reg # 102255
	Remarks of the Evaluator	
	Decision: Approved	
179.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Falbenda 360 Bolous**
	Composition	Each Bolus Contains:- Albendazole……. 360mg.
	Diary No. Date of R& I & fee	Dy No. 22755: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications

	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Alvwnax-360 Bolus (Star Labs) Reg # 049552
	Remarks of the Evaluator	
	Decision: Approved	
180.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Falbenda 1500 Bolous**
	Composition	Each Bolus Contains:- Albendazole……. 1500mg
	Diary No. Date of R& I & fee	Dy No.22756: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	VetyAlben Bolus 1500 (Leads Pharma) Reg # 058856
	Remarks of the Evaluator	
	Decision: Approved	
181.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Falbenda 300 Bolous**
	Composition	Each Bolus Contains:- Albendazole……. 300mg. `
	Diary No. Date of R& I & fee	Dy No.22757: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	AlbendazoleBolous Bolus (Prix Pharma) Reg # 075645
	Remarks of the Evaluator	
	Decision: Approved	
182.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**ClosoBolous**
	Composition	EACH BOLUS CONTAINS:- Closental…….500mg
	Diary No. Date of R& I & fee	Dy No.22758: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	I ZentalBolous (International Pharma) Reg # 073928
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
183.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Ramsol 2000 Bolous**

	Composition	Each Bolus Contains:- Tetramisole Hcl……. 2000mg.
	Diary No. Date of R& I & fee	Dy No. 22759: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Tramiz 2.0 Bolus (International Pharma) Reg # 094407
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
184.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Ramsol 150 Bolous**
	Composition	Each Bolus Contains:- Tetramisole Hcl……. 150mg.
	Diary No. Date of R& I & fee	Dy No.22760: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Tramiz Forte Bolus (International Pharma) Reg # 094408
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
185.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Ramsol 600 Bolous**
	Composition	EACH BOLUS CONTAINS:- Tetramisole hcl……. 600MG.
	Diary No. Date of R& I & fee	Dy No.22761: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Tramiz 600 Bolus (International Pharma) Reg # 094409
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
186.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Ramsol 1000 Bolous**
	Composition	EACH BOLUS CONTAINS:- Tetramisolehcl……. 1000MG.
	Diary No. Date of R& I & fee	Dy No.22762: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product specifically cation	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s

	Me-too status (with strength and dosage form)	Tramiz DS Bolus (International Pharma) Reg # 094410
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
187.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Famisol 600 Bolous**
	Composition	EACH BOLUS CONTAINS:- Levamisole Hcl……. 600MG.
	Diary No. Date of R& I & fee	Dy No.22763: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Zeus 600 Forte Bolus (International Pharma) Reg # 094413
	Remarks of the Evaluator	
	Decision: Approved	
188.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Famisol 184 Bolous**
	Composition	EACH BOLUS CONTAINS:- Levamisole Hcl……. 184MG.
	Diary No. Date of R& I & fee	Dy No.22764: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Zeus 184 Bolus (International Pharma) Reg # 094414
	Remarks of the Evaluator	
	Decision: Approved	
189.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Famisol 1125 Bolous**
	Composition	EACH BOLUS CONTAINS:- Levamisole Hcl……. 1125MG.
	Diary No. Date of R& I & fee	Dy No.22765: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Zeus 1125 Bolus (International Pharma) Reg # 094415
	Remarks of the Evaluator	
	Decision: Approved	
190.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Famisol300 Bolous**
	Composition	EACH BOLUS CONTAINS:- Levamisole Hydrochloride ……. 300MG.
	Diary No. Date of R& I & fee	Dy No.22766: 11.08.2022

		PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Leva 300 Bolus (Intervac Pharma) Reg # 073987
	Remarks of the Evaluator	
	Decision: Approved	
191.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Famisol 400 Bolous**
	Composition	EACH BOLUS CONTAINS:- Levamisole Hcl……. 400MG.
	Diary No. Date of R& I & fee	Dy No.22767 : 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Leva Par Bolus (Grand Pharma) Reg # 102063
	Remarks of the Evaluator	
	Decision: Approved	
192.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**OCS Bolous**
	Composition	Each Bolus Contains: - Oxyclozanide……..625mg Oxfendazole……275mg Cobalt Sulphate…….30mg Sodium Selenite……..30mg
	Diary No. Date of R& I & fee	Dy No. 22768: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic Minerals
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Galied Bolus (International Pharma) Reg # 078222
	Remarks of the Evaluator	Generic Not Confirmed
	Decision: Approved with innovator's specifications	
193.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Teranide Forte Bolous**
	Composition	Each Bolus Contains:- Tetramisole HCL……2g Oxyclozanide……...1.4g
	Diary No. Date of R& I & fee	Dy No.22769: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Combat Bolous (Prix Pharma) Reg # 063680
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications	
194.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**TeranideBolous**
	Composition	Each Bolus Contains:- Tetramisole……0.450g Oxyclozanide……...0.450g
	Diary No. Date of R& I & fee	Dy No. 22770: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Combat Bolus (Prix Pharma) Reg # 063681
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
195.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**FafenBolous**
	Composition	Each Bolus Contains: - Fenbendazole ……750mg
	Diary No. Date of R& I & fee	Dy No.22771: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Fenbal Bolus (Wiamts Pharma) Reg # 078319
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
196.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F-Tricla 900 Bolous**
	Composition	Each Bolus Contains: - Triclabendazole ……..900.00mg
	Diary No. Date of R& I & fee	Dy No.22772: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	CEREX Bolus (Prix Pharma) Reg # 035068
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
197.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F-Tricla 250 Bolous**
	Composition	Each Bolus Contains:- Triclabendazole ……..250.00mg
	Diary No. Date of R& I & fee	Dy No.22773: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications

	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Fasisym-250Bolus (Symans Pharma) Reg # 062116
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
198.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**ClobenBolous**
	Composition	Each Bolus Contains: - Closantel….350mg Mebendazole….525mg
	Diary No. Date of R& I & fee	Dy No.22774: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Clomeb Bolus (Prix Pharma) Reg # 057066
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
199.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**L-Bith Bolus**
	Composition	Each Bolus Contains:- Bithional sulfoxide……4gm Levamisole Hydrochloride…….0.6gm
	Diary No. Date of R& I & fee	Dy No. 22775: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10`s , 20`s 50`s , 100`s
	Me-too status (with strength and dosage form)	Bithnisol Bolus (Leads Pharma) Reg # 063676
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	

Oral Liquid Section-II (General Veterinary) Additional		
11 Products / 8 Molecules		
200.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F.MEC 0.24% Drench**
	Composition	Each ml Contains:- Ivermectin ……0.24%
	Diary No. Date of R& I & fee	Dy No.22728: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	Elvomec Drench 0.24% (Elko Organization) Reg # 063730
	Remarks of the Evaluator	
	Decision:Approved	

201.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F.MEC Super Drench**
	Composition	EACH ML CONTAINS:- IVERMECTIN ……1%
	Diary No. Date of R& I & fee	Dy No.22729: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	Ivosol Drench (BioGen Pharma) Reg # 069608
	Remarks of the Evaluator	
	Decision: Approved	
202.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F.MEC Plus Drench**
	Composition	Each ml Contains:- Ivermectin ……0.8mg
	Diary No. Date of R& I & fee	Dy No.22730: 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Anti parasitic Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	VERMOK Drench (ATTABAK Pharma) Reg # 062182
	Remarks of the Evaluator	
	Decision: Approved	
203.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**F SCOUR Drench**
	Composition	EACH ML CONTAINS:- Sulphadiazine …….35.5mg Sulphadiamidine …28.4mg Neomycin Sulphate ..1.8mg Hyosine Methylbromide……0.04mg Pectin ……..7.1mg Kaolin …….103.3mg Vitamin B1 ……0.15mg Vitamin B2…….0.22mg
	Diary No. Date of R& I & fee	Dy No.22731; 11.08.2022 PKR. 30,000/-; 11.08.2022
	Pharmacological Group	Antibiotic, Anti diarrheals
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	Biviscour Liquid(Hawk Bio Pharma) Reg # 079110
	Remarks of the Evaluator	Sulphadiazine salt form is not as per reference
	Decision: Approved with Innovator specifications. Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

204.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Emifen 24 Oral Liquid**
	Composition	Each 100ml Contains:- Enrofloxacin Bp……..……..10gm Aminophylline……...4gm Guaiphenesin Bp…….10gm
	Diary No. Date of R& I & fee	Dy No.22732: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Antibiotic, Broncho dilators
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	ENROPHYLIN ORAL LIQUID (BAARIQ PHARMA)080730
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
205.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Emifen Forte Oral Liquid**
	Composition	Each Ml Contains:- Enrofloxacin ……. 100mg. Aminophyllin. 100mg. Guaiphenesin… 40mg.
	Diary No. Date of R& I & fee	Dy No.22733: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Antibiotic, Broncho dilators
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	ENSOL –AG Oral Liquid (BioGen Pharma) Reg # 049720
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
206.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**P 10 10% Oral Liquid**
	Composition	Each Litre Contains Pefloxacin Methanesulfonate Eq To Pefloxacin ……..... 100gm
	Diary No. Date of R& I & fee	Dy No.22734: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Antibiotic,
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	Peperoxin (Samyang Korea) 82807
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
207.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur

	Brand Name +Dosage Form + Strength	**OT-ZOLE DRENCH**
	Composition	EACH LITER CONTAINS: - Oxfendazole ……22.65gm Triclabendazole……85gm
	Diary No. Date of R& I & fee	Dy No. 22738: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	Vorcid Suspension (ICI PAKISTAN) 063563
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
208.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Fagonide 3.4 Oral DRENCH**
	Composition	EACH 100ML OF SUSPENSION CONTAINS. OXYCLOZANIDE…….3.4%
	Diary No. Date of R& I & fee	Dy No.22735: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	Clozak Suspension (Attabak Pharma) 053911
	Remarks of the Evaluator	
	Decision: Approved	
209.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Cyper-F Oral Liquid**
	Composition	Each Liter Contains:- Cypermethrin…….100gm
	Diary No. Date of R& I & fee	Dy No.22736: 11.08.2022 PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Insecticide
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	Cypercid Liquid (Breeze Pharma) 063798
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
210.	**Name and address of manufacturer / Applicant**	M/s FARM AID GROUP of Plot No 3/2 Phase I&II Hattar Industrial Estate Haripur
	Brand Name +Dosage Form + Strength	**Ben T Drench**
	Composition	Each 100ml Contains:- Triclabendazole….12gm Ivermectin…….0.2gm Albendazole…….10gm
	Diary No. Date of R& I & fee	Dy No. 22737 : 11.08.2022

		PKR. 30,000/-; 10.08.2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	30ml,50ml,100ml,120ml,250ml,500ml,1Litre,5Litre
	Me-too status (with strength and dosage form)	Thunder Drench (Star Labs) 058941
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	

Agenda of Evaluator PEC-III

Case No. 01 Registration applications of New section / New License

Case No. 01: M/s Akhsah Pharmaceuticals (Pvt) Ltd, Rawat.

Firm has submitted copy of Drug Manufacturing License (DML No. 000943) issued dated 14-09-2021 along with letter of issuance of Drug Manufacturing License dated 14-09-2021. The letter specifies following section:
1. Tablet Section (General)
2. Capsule Section (General)
3. Cream/Ointmnt section (General)

Now the firm has submitted following applications as per the details mentioned in the table below:

Name of Section	No of molecules	No of products
Tablet Section (General)	02	04
Capsule Section (General)	05	08
Cream/Ointmnt section (General)	-	-

Capsule Section (General): 05 Molecules / 08 Products

211.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18961: 29-06-2022
	Details of fee submitted	PKR 30,000/- : 27-06-2022
	The proposed proprietary name / brand name	**OMICA 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Omeprazole (as enteric coated pellets)…..20mg
	Pharmaceutical form of applied drug	Off white spherical shaped enteric coated pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Risek Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Omega capsule of Feroesons Lab. Firm has submitted results of CDP for their product against the comparator product Omega capsule of Feroesons Lab.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	OMP1131		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/O20	CP-02/O20	CP-03/O20
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	22-02-2022	22-02-2022	22-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 26-11-2021 specifying purchase of 4Kg 8.5% Omeprazole EC pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm

1.	Justify why the drug substance specifications of the drug substance manufacturer is different from USP monograph. Further justify performing assay test by HPLC method using different column, flow rate and injection volume from that specified in USP monograph.	We performed the assay of Omica 20mg Capsule by HPLC according to USP monograph, and our column was expired so that is why we change the old with new one having same specifications i.e dimension, length and pore size. **Firm has not submitted any revised analytical method and any relevant analytical record.**
2.	Justify why the drug substance specifications of the drug product manufacturer are different from the specifications of drug substance manufacturer as well as USP pharmacopoeia. Your specifications do not include analytical method for dissolution test.	We performed dissolution according to USP monograph and we must have revised our SAP and dissolution method according to USP monograph. **The submitted dissolution specification by the firm are different from USP.**
3.	Provide verification studies of drug substance from drug product manufacturer.	As omeprazole 8.5% pellets are ready to fill capsule and we performed analytical method verification at drug product stage so please consider it.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number OMP1131 from both API manufacturer as well as drug product manufacturer
5.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
6.	Your CDP results show that the average drug release at 30-minute time point in 6.8pH phosphate buffer is 59.31%, and at 60 minutes is 74.39% while as per USP monograph the drug product should exhibit more than 75%(Q) drug release in 30 minutes at 6.8 pH phosphate buffer in test-1. Justify how your product can comply USP specifications and can have comparable drug release as that of innovator drug product.	We showed the comparison of our product which are released in 30 minutes, in 6.8 phosphate buffer is 59.31% and reference product at same condition released 60.26% so the similarity factors between reference product and sample product are in limit and comply the USP specification. **Innovator product, USP as well as API manufacturer specify that the drug should exhibit more than 75%(Q) drug release in 30 minutes at 6.8 pH phosphate buffer.**
7.	Specify the exact dissolution test for your drug product specifications, since USP has mentioned two different tests for dissolutionin which acceptance criteria as well as analytical methods are different.	We followed the USP monograph dissolution method Test 2 for omica 20mg capsules. **The details of analytical method submitted by the firm were different from USP test-2.**
8.	You have mentioned dissolution test acceptance criteria as NLT 75%(Q) in 30 minutes, while in stability studies you have mentioned the dissolution acceptance criteria as NLT75% in 45 minutes.	The acceptance criteria for dissolution is NLT 75% (Q) in 45 minutes according to USP monograph test-2. **The provided analytical method by the firm was not as per USP test-2.**
9.	Your analytical method submitted in section 3.2.P.5.2 has provided dissolution test method and formula for HPLC while in stability studies you have perfomed dissolution test using UV	The assay of omica 20mg capsule are performed by HPLC according to USP monograph and acid stage dissolution is also performed by recovery method on HPLC and buffer stage is performed on UV.

	method. Clarification is required in this regard.	**Firm has performed dissolution test as per UV method in the stability studies.**
10.	Provide details about the HPLC system, total number of HPLC system along with details of its software and model.	We have total 2 HPLC systems. One is Perkin Elmer Series 200 from start of the day which is American made, auto sampler, quaternary gradient, 21st CFR compliance and can accommodate 100sample/vials at a time having UV detector and operate by Total Chrome software. After some times we purchase another HPLC unit i.e Water Alliance separation module model 2695, American made, auto sampler ,quaternary gradient, 21st CFR compliance having the capacity of 120 samples /vials at a time, equipped with Photodiode Array detector and operate by Empower 2 software.
11.	Provide details about the stability chambers, total number of chambers including details of the model and capacity for each.	We have total 4 stability chambers 2 are made by Galvano Scientific model STC-SS-400-LAC having capacity of 250 liters. 2 are made by Varoline Intercooler model SSS-15R having capacity of 500 liters.
12.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 26-11-2021 specifying purchase of 4Kg 8.5% Omeprazole EC pellets.

Decision: Approved. Registration Board decided as follows:

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter shall be issued upon submission of following documents:**
  - **a. Results of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product i.e. Losec 20mg Capsule.**
  - **b. Performance of dissolution test as per USP test-2 method at next time point of Long term stability studies.**
  - **c. Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

212.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19519: 04-07-2022
	Details of fee submitted	PKR 30,000/- : 27-06-2022
	The proposed proprietary name / brand name	**OMICA 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Omeprazole (as enteric coated pellets)…..40mg
	Pharmaceutical form of applied drug	Off white spherical shaped enteric coated pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Risek Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Omega capsule of Feroesons Lab. Firm has submitted results of CDP for their product against the comparator product Omega capsule of Feroesons Lab.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	OMP1141		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/40	CP-02/O20	CP-03/O20
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	22-02-2022	22-02-2022	22-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 26-11-2021 specifying purchase of 3Kg 22.5% Omeprazole EC pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify why the drug substance specifications of the drug substance	We performed the assay of Omica 40mg Capsule by HPLC according to USP monograph, and our column

	manufacturer is different from USP monograph. Further justify performing assay test by HPLC method using different column, flow rate and injection volume from that specified in USP monograph.	was expired so that is why we change the old with new one having same specifications i.e dimension, length and pore size. **Firm has not submitted any revised analytical method and any relevant analytical record.**
2.	Justify why the drug substance specifications of the drug product manufacturer are different from the specifications of drug substance manufacturer as well as USP pharmacopoeia. Your specifications do not include analytical method for dissolution test.	We performed dissolution according to USP monograph and we must have revised our SAP and dissolution method according to USP monograph. **The submitted dissolution specification by the firm are different from USP.**
3.	Provide verification studies of drug substance from drug product manufacturer.	As omeprazole 22.5% pellets are ready to fill capsule and we performed analytical method verification at drug product stage so please consider it.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number OMP1141 from both API manufacturer as well as drug product manufacturer
5.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
6.	Justify how exactly same results of CDP studies are reported for both 20mg capsule and 40mg capsule when tested against omega capsule of Ferozesons Laboratories.	Onward we performed the CDP studies carefully according to DRAP guideline as well as FDA. **Firm has not submitted complete results of CDP studies.**
7.	Specify the exact dissolution test for your drug product specifications, since USP has mentioned two different tests for dissolutionin which acceptance criteria as well as analytical methods are different.	We followed the USP monograph dissolution method Test 2 for omica 20mg capsules. **The details of analytical method submitted by the firm were different from USP test-2.**
8.	You have mentioned dissolution test acceptance criteria as NLT 75%(Q) in 30 minutes, while in stability studies you have mentioned the dissolution acceptance criteria as NLT75% in 45 minutes.	The acceptance criteria for dissolution is NLT 75% (Q) in 45 minutes according to USP monograph test-2. **The provided analytical method by the firm was not as per USP test-2.**
9.	Your analytical method submitted in section 3.2.P.5.2 has provided dissolution test method and formula for HPLC while in stability studies you have perfomed dissolution test using UV method. Clarification is required in this regard.	The assay of omica 20mg capsule are performed by HPLC according to USP monograph and acid stage dissolution is also performed by recovery method on HPLC and buffer stage is performed on UV. **Firm has performed dissolution test as per UV method in the stability studies.**
10.	Provide details about the HPLC system, total number of HPLC system along with details of its software and model.	We have total 2 HPLC systems. One is Perkin Elmer Series 200 from start of the day which is American made, auto sampler, quaternary gradient, 21st CFR compliance and can accommodate 100sample/vials at a time having UV detector and operate by Total Chrome software.

		After some times we purchase another HPLC unit i.e Water Alliance separation module model 2695, American made, auto sampler ,quaternary gradient, 21st CFR compliance having the capacity of 120 samples /vials at a time, equipped with Photodiode Array detector and operate by Empower 2 software.
11.	Provide details about the stability chambers, total number of chambers including details of the model and capacity for each.	We have total 4 stability chambers 2 are made by Galvano Scientific model STC-SS-400-LAC having capacity of 250 liters. 2 are made by Varoline Intercooler model SSS-15R having capacity of 500 liters.
12.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 26-11-2021 specifying purchase of 3Kg 22.5% Omeprazole EC pellets.

Decision: Approved. Registration Board decided as follows:

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter shall be issued upon submission of following documents:**
  - **a. Results of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's , /comparator product.**
  - **b. Performance of dissolution test as per USP test-2 method at next time point of Long term stability studies.**
  - **c. Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**

213.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10884: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 28-04-2022
	The proposed proprietary name / brand name	**ESOX 20mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Esomeprazole magnesium trihydrate enteric coated pellets eq to esomeprazole…..20mg
	Pharmaceutical form of applied drug	Off white spherical shaped enteric coated pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Nexum Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Esocue capsule of Sandoz Pharma. Firm has submitted results of CDP for their product against the comparator product Esocue capsule of Sandoz Pharma.

	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	EMZ046406		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/E20	CP-02/E20	CP-03/E20
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	21-01-2022	21-01-2022	21-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 26-11-2021 specifying purchase of 4Kg 8.5% esomeprazole EC pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide verification studies of drug substance from drug product manufacturer.	As esomeprazole 8.5% pellets are ready to fill capsule and we performed analytical method verification at drug product stage so please consider that.
2.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number EMZ046406 from both API manufacturer as well as drug product manufacturer

3.	Justify how 1.178mg of esomeprazole magnesium trihydrate 8.5% EC pellets are equivalent to 20mg esomeprazole.	Theoretical filled weight of esox 20mg capsule is 235.29mg which are equivalent to 20mg of esomeprazole magnesium trihydrate. Our batch size is 5000 capsules, so for such batch size we need 1.176 kg of esomeprazole. **Firm has not justified fill weight per capule.**
4.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
5.	Your CDP results show that the average drug release at 30-minute time point in 6.8pH phosphate buffer is 59.31%, while as per USP monograph the drug product should exhibit more than 75%(Q) drug release in 30 minutes at 6.8 pH phosphate buffer. Justify how your product can comply USP specifications and can have comparable drug release as that of innovator drug product.	We showed the comparison of our product which are released in 30 minutes, in 6.8 phosphate buffer is 59.31% and reference product at same condition released 60.26% so the similarity factors between reference product and sample product are in limit and comply the USP specification. **As per Innovator product, USP as well as API manufacturer the drug should exhibit more than 75%(Q) drug release in 30 minutes at 6.8 pH phosphate buffer, but the CDP results of the firm are contrary to this.**
6.	Justify the drug product specifications submitted in section 3.2.P.5.2 in which you have performed dissolution testing in acid stage using UV method, while USP monograph specifies that dissolution testing to be performed using HPLC method.	On 6th month stability we performed proper testing according to USP monograph on HPLC. **Firm has not submitted revised analytical method as well as analytical record for dissolution testing through HPLC.**
7.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 26-11-2021 specifying purchase of 4Kg 8.5% esomeprazole EC pellets.

Decision: Approved. Registration Board decided as follows:

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **For commerical batches, manufacturer shall apply the actual potency determined by drug substance analysis for the calculation of fill weight of Esomeprazole pellets per capsule**
- **Registration letter shall be issued upon submission of following documents:**
  a. **Results of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's/comparator product.**
  b. **Performance of dissolution test as per USP monograph at next time point of Long term stability studies.**
  c. **Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**

214.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10885: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 28-04-2022
	The proposed proprietary name / brand name	**ESOX 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Esomeprazole magnesium trihydrate enteric coated pellets eq to esomeprazole…..40mg
	Pharmaceutical form of applied drug	Off white spherical shaped enteric coated pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Nexum Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Esocue capsule of Sandoz Pharma. Firm has submitted results of CDP for their product against the comparator product Esocue capsule of Sandoz Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

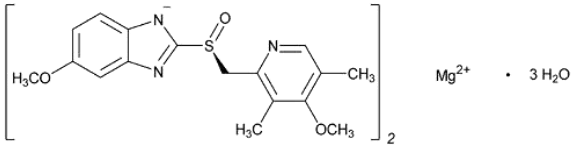
Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	EMZ046404		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/E40	CP-02/E40	CP-03/E40
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	21-01-2022	21-01-2022	21-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 26-11-2021 specifying purchase of 3Kg 22.5% esomeprazole EC pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm

		has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide verification studies of drug substance from drug product manufacturer.	As esomeprazole 22.5% pellets are ready to fill capsule and we performed analytical method verification at drug product stage so please consider that.
2.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number EMZ046404 from both API manufacturer as well as drug product manufacturer
3.	Justify how 177.7mg of esomeprazole magnesium trihydrate 22.5% EC pellets are equivalent to 40mg esomeprazole.	Theoretical filled weight of esox 40mg capsule are 177.77mg which are equivalent to 40mg of esomeprazole magnesium trihydrate and we have 22.5% pellet so 100/22.5 x 40 =177.77mg.  **The capsule shall contain 40mg of esomeprazole and the actual salt form is esomeprazole magnesium trihydrate. The API manufacturer has provided 22.5% esomeprazole magnesium. As evident from the structure, two molecules of esomeprazole are joined with a single magnesium to make esomeprazole magnesium. That's why calculation of fill weight shall take into consideration all these things before making the final formulation.**
4.	You have specified API lot number EMZ046406 as 8.5% EC pellets in ESOX 20mg Capsule application and also provided COA of the same lot of API i.e. EMZ046406 as 22.5% EC pellets in ESOX 40mg Capsule	API lot number for esomeprazole 8.5% pellets in esox 20mg capsules are EMZ046406 while for esomeprazole 22.5% pellets in esox 40mg Caps are EMZ046404.
5.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
6.	Your CDP results show that the average drug release at 30-minute time point in 6.8pH phosphate buffer is 67.59%, while as per USP monograph the drug product should exhibit more than 75%(Q) drug release in 30 minutes at 6.8 pH	We showed the comparison of our product which are released in 30 minutes, in 6.8 phosphate buffer is 67.59% and reference product at same condition released 68.12% so the similarity factors between reference product and sample product are in limit and comply the USP specification.

	phosphate buffer. Justify how your product can comply USP specifications and can have comparable drug release as that of innovator drug product.	**As per Innovator product, USP as well as API manufacturer the drug should exhibit more than 75%(Q) drug release in 30 minutes at 6.8 pH phosphate buffer, but the CDP results of the firm are contrary to this.**
7.	Justify the drug product specifications submitted in section 3.2.P.5.2 in which you have performed dissolution testing in acid stage using UV method, while USP monograph specifies that dissolution testing to be performed using HPLC method.	On 6th month stability we performed proper testing according to USP monograph on HPLC. **Firm has not submitted revised analytical method as well as analytical record for dissolution testing through HPLC.**
8.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 26-11-2021 specifying purchase of 3Kg 22.5% esomeprazole EC pellets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **For commerical batches, manufacturer shall apply the actual potency determined by drug substance analysis for the calculation of fill weight of Esomeprazole pellets per capsule**
- **Registration Board further decided that registration letter shall be issued upon submission of following:**

i. **Results of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's/comparator product.**
ii. **Performance of dissolution test as per USP monograph at next time point of Long term stability studies.**
iii. **Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

215.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 10886: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 28-04-2022
	The proposed proprietary name / brand name	**DENSA 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Dexlansoprazole (as dual delayed release pellets)…..30mg
	Pharmaceutical form of applied drug	White to off white spherical pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product

		against the comparator product Delanzo capsule of Sami Pharmaceuticals. Firm has submitted results of CDP for their product against the comparator product Delanzo capsule of Sami Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	DSL825		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/D30	CP-02/D30	CP-03/D30
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	21-01-2022	21-01-2022	21-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 29-11-2021 specifying purchase of 7Kg 22.5% dexlansoprazole DDR pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance	Submission of data in section 3.2.S.4.1 as per DRAP guideline which specifies that copies of drug substance specification and analytical procedure used for routine

	specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	testing of drug substance by both drug substance and drug product manufacturer is provided.
2.	Provide verification studies of drug substance from drug product manufacturer.	As we have used ready to fill pellets and has same specification of raw material and filled capsule and we have performed verification in product stage so please consider it as verification.
3.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number DSL825 from both API manufacturer as well as drug product manufacturer
4.	Justify why pharmaceutical equivalence studies does not include dissolution test.	In pharmaceutical equivalence study we have performed dissolution but mistakenly not include in the report, now the firm has submitted the report.
5.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
6.	The innovator product is available as dual delayed release pellets in HPMC capsule shells while your product is in hard gelatin capsule shells. Justification is required in this regard.	The innovator product is available as delay released pellets in HPMC capsule shell while our product is in hard gelatin capsule shell we have performed stability studies there is no effect of capsule shell in stability study
7.	The drug substance manufacturer specifies that dissolution testing in buffer stage is to be carried out at 284nm, while you have specified dissolution testing in buffer at 292nm. Justification is required in this regard.	According to drug substance manufacturer the wavelength of dissolution of dexlansoprazole in buffer stage at about 284nm we revised our SAP as per drug substance manufacturer and set wavelength about 292nm in our revised SAP but next time we change our revised SAP about 284nm. **Firm has not submitted revised analytical method or relevant analytical record.**
8.	You have used a different HPLC column for assay testing of the drug product from that recommended by drug substance manufacturer. Justification is required in this regard.	We performed the assay of Densa 30mg Capsule by HPLC according to **USP monograph**, and our column was expired so that is why we change the old with new one having same specifications i.e dimension, length and pore size. **USP monograph for the applied product does not exist, moreover no analytical record is submitted which shows that the HPLc column have been changed. Moreover the verification studies are performed at old column.**
9.	Provide stability data sheets for accelerated and real time stability studies results for the three batches, since your results sheets are not properly arranged.	Firm has submitted stability data sheets for accelerated and real time stability studies results for the three batches
10.	Justify the assay testing of drug product using UV method, since the innovator product as well as drug substance manufacturer specifies HPLC method for assay testing.	We performed the assay on UV method according to drug substance manufacturer UV method. Drug substance manufacturer specifies HPLC method as well as UV method for assay which is already provided.
11.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 29-11-2021 specifying purchase of 7Kg 22.5% dexlansoprazole DDR pellets.

Decision: Deferred for following: • **Submission of stability study data of the drug product at next time on revised specifications and analytical method in which assay test is performed using HPLC method since applied poduct is non pharmacopoeial and drug substance manufacturer has applied HPLC method for the Assay test of Dexlansoprazole pellets.** • **Submission of 7500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
216.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10887: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 28-04-2022
	The proposed proprietary name / brand name	**DENSA 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Dexlansoprazole (as dual delayed release pellets)…..60mg
	Pharmaceutical form of applied drug	White to off white spherical pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Delanzo capsule of Sami Pharmaceuticals. Firm has submitted results of CDP for their product against the comparator product Delanzo capsule of Sami Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	DSL825		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/D60	CP-02/D60	CP-03/D60
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule

Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	21-01-2022	21-01-2022	21-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 29-11-2021 specifying purchase of 7Kg 22.5% dexlansoprazole DDR pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submission of data in section 3.2.S.4.1 as per DRAP guideline which specifies that copies of drug substance specification and analytical procedure used for routine testing of drug substance by both drug substance and drug product manufacturer is provided.
2.	Provide verification studies of drug substance from drug product manufacturer.	As we have used ready to fill pellets and has same specification of raw material and filled capsule and we have performed verification in product stage so please consider it as verification.
3.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number DSL825 from both API manufacturer as well as drug product manufacturer
4.	Justify why pharmaceutical equivalence studies does not include dissolution test.	In pharmaceutical equivalence study we have performed dissolution but mistakenly not include in the report, now the firm has submitted the report.
5.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
6.	The innovator product is available as dual delayed release pellets in HPMC capsule shells while your product is in	The innovator product is available as delay released pellets in HPMC capsule shell while our product is in hard gelatin capsule shell we have performed stability

	hard gelatin capsule shells. Justification is required in this regard.	studies there is no effect of capsule shell in stability study
7.	The drug substance manufacturer specifies that dissolution testing in buffer stage is to be carried out at 284nm, while you have specified dissolution testing in buffer at 292nm. Justification is required in this regard.	According to drug substance manufacturer the wavelength of dissolution of dexlansoprazole in buffer stage at about 284nm we revised our SAP as per drug substance manufacturer and set wavelength about 292nm in our revised SAP but next time we change our revised SAP about 284nm. **Firm has not submitted revised analytical method or relevant analytical record.**
8.	You have used a different HPLC column for assay testing of the drug product from that recommended by drug substance manufacturer. Justification is required in this regard.	We performed the assay of Densa 30mg Capsule by HPLC according to **USP monograph**, and our column was expired so that is why we change the old with new one having same specifications i.e dimension, length and pore size. **USP monograph for the applied product does not exist, moreover no analytical record is submitted which shows that the HPLc column have been changed. Moreover the verification studies are performed at old column.**
9.	Provide stability data sheets for accelerated and real time stability studies results for the three batches, since your results sheets are not properly arranged.	Firm has submitted stability data sheets for accelerated and real time stability studies results for the three batches
10.	Justify the assay testing of drug product using UV method, since the innovator product as well as drug substance manufacturer specifies HPLC method for assay testing.	We performed the assay on UV method according to drug substance manufacturer UV method. Drug substance manufacturer specifies HPLC method as well as UV method for assay which is already provided.
11.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 29-11-2021 specifying purchase of 7Kg 22.5% dexlansoprazole DDR pellets.

Decision: Deferred for following:

- **Submission of stability study data of the drug product at next time on revised specifications and analytical method in which assay test is performed using HPLC method since applied poduct is non pharmacopoeial and drug substance manufacturer has applied HPLC method for the Assay test of Dexlansoprazole pellets.**
- **Submission of 7500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

217.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12815: 25-05-2022
	Details of fee submitted	PKR 30,000/- : 12-05-2022
	The proposed proprietary name / brand name	**RESOL 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Itraconazole (as IR pellets)…..100mg
	Pharmaceutical form of applied drug	Off white spherical shaped immediate release pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Azole antifungals
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 4's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Icon Capsule by Ferozesons Lab
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Icon capsule of Feroesons Lab. Firm has submitted results of CDP for their product against the comparator product Icon capsule of Feroesons Lab.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	ICZ1489		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/L100	CP-02/L100	CP-03/L100
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	28-01-2022	28-01-2022	28-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 13-12-2021 specifying purchase of 7Kg 22.0% Itraconazole IR pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm

1.	Provide verification studies of drug substance from drug product manufacturer.	Itraconazole pellets are ready to fill and drug substance specification is same as drug product, we have performed on drtug product stage.
2.	Provide stability study data of three batches of drug substance as per zone IV-A conditions, since the submitted real time stability study data is only for 6 months.	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
3.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number ICZ1489 from both API manufacturer as well as drug product manufacturer
4.	Your CDP results submitted for itraconazole capsule is exactly same as that submitted in omeprazole 20mg and omeprazole 40mg capsule application.	Onward we performed the CDP studies carefully according to DRAP guideline as well as FDA. **Firm has not submitted complete results of CDP studies.**
5.	Specify the exact dissolution test for your drug product specifications, since USP has mentioned two different tests for dissolutionin which acceptance criteria as well as analytical methods are different.	For itraconazol capsule we have performed dissolution test 1.
6.	Your analytical method specfies that dissolution test is through UV method while in stability studies you have performed dissolution test at HPLC.	According to USP dissolution method of itraconazol is on UV method but we have performed it on HPLC using same parameters followed in assay.
7.	Justify how same standard solution chromatograms are used for dissolution and assay test in stability studies.	We performed dissolution and assay on HPLC makes same concentration for assay as well as dissolution.
8.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 13-12-2021 specifying purchase of 7Kg 22.0% Itraconazole IR pellets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **For commerical batches, manufacturer shall apply the actual potency determined by drug substance analysis for the calculation of fill weight of Esomeprazole pellets per capsule.**
- **Registration Board further decided that registration letter shall be issued upon submission of following:**

a. Results of Comparative Dissolution Profile (CDP) against the innovator's/comparator product.
b. Performance of dissolution test as per USP monograph at next time point of Long term stability studies.
c. Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

218.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12816: 25-05-2022
	Details of fee submitted	PKR 30,000/- : 12-05-2022
	The proposed proprietary name / brand name	**LANSA 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Lansoprazole…..30mg
	Pharmaceutical form of applied drug	Off white spherical shaped enteric coated pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Selanz SR Capsule by Searle
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product QPro capsule of Bosch Pharma. Firm has submitted results of CDP for their product against the comparator product QPro capsule of Bosch Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.		
API Lot No.	LPS0379		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/L30	CP-02/L30	CP-03/L30
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	28-01-2022	28-01-2022	28-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-12-2021 specifying purchase of 6Kg 8.5% Lansoprazole EC pellets.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify why the drug substance specifications of the drug substance manufacturer is different from USP monograph. Further justify the assay test using UV method while USP recommends HPLC assay for assay test.	Specification of drug substance manufacture are provided and we will also must be followed the USP monograph as we followed in 6th month stability studies. **The submitted specifications are not as per USP. No revised specifications are submitted by the firm.**
2.	Justify why the drug substance specifications of the drug product manufacturer are different from the specifications of drug substance manufacturer as well as USP pharmacopoeia. Your specifications do not include dissolution test at buffer stage, clarification is required in this regard.	We revised our testing method according to USP monograph and we have performed buffer stage dissolution in 6th month stability. **The submitted specifications are not as per USP. No revised specifications are submitted by the firm.**
3.	Provide verification studies of drug substance from drug product manufacturer.	As lansoprazole enteric coated pellets are ready to fill capsule and we performed analytical method verification at drug product stage so please consider him.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number LPS0379 from both API manufacturer as well as drug product manufacturer
5.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
6.	Your CDP results show that the average drug release at 60-minute time point in 6.8pH phosphate buffer is 78.46%, while as per USP monograph the drug product should exhibit more than 80% drug release in 60 minutes at 6.8 pH phosphate buffer. Justify how your product can comply USP specifications and can have comparable drug release as that of innovator drug product.	The comparison of our product which are released in 60 minutes, in 6.8 phosphate buffer is 78.46% and reference product at same condition released 78.53% so the similarity factors between reference product and sample product are in limit and comply the USP specification. **As per Innovator product, USP as well as API manufacturer the drug should exhibit more than 80% drug release in 60 minutes at 6.8 pH phosphate buffer, but the CDP results of the firm are contrary to this.**
7.	Justify the drug product specifications submitted in section 3.2.P.5.2 in which you have performed dissolution testing	According to USP monograph the wavelength of lansoprazole buffer stage dissolution is about 286 and

	in buffer stage using UV method at 306nm, while USP monograph specifies that testing to be performed using UV method at about 286 and 650 nm.	650 nm we revised our SAP as per USP monograph and set wavelength about 332 nm in our revised SAP. **Firm has not submitted revised analytical method as well as analytical record for dissolution testing through HPLC.**
8.	Justify why you have used different HPLC column for product testing than that specified in USP monograph.	On 6th month stability we used specific column described in USP monograph and also revised our method. **Firm has not submitted revised analytical method as well as analytical record for dissolution testing through HPLC.**
9.	You have specified dissolution acceptance criteria as NLT 80% in 60 minutes in buffer stage, while in stability studies you have specified acceptance criteria as NLT 80% in 30 minutes. Justification is required in this regard.	We revised our method according to USP monograph and also performed dissolution according to pharmacopeia on 6th month. **Firm has not submitted revised analytical method as well as analytical record for dissolution testing through HPLC.**
10.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 10-12-2021 specifying purchase of 6Kg 8.5% Lansoprazole EC pellets.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **For commerical batches, manufacturer shall apply the actual potency determined by drug substance analysis for the calculation of fill weight of Esomeprazole pellets per capsule.**
- **Registration Board further decided that registration letter shall be issued upon submission of following:**

a. Results of Comparative Dissolution Profile (CDP) against the innovator's/comparator product.
b. Performance of dissolution test as per USP monograph at next time point of Long term stability studies.
c. Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Tablet Section (General): 02 Molecules / 04 Products

219.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19520: 04-07-2022
	Details of fee submitted	PKR 30,000/- : 27-06-2022
	The proposed proprietary name / brand name	**MOXIP 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated contains: Moxifloxacin (as HCl)..…..400mg
	Pharmaceutical form of applied drug	Yellow oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Moxiget Tablets by Getz
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product

		against the comparator product Moxiget Tablet of Getz Pharmaceuticals. Firm has submitted results of CDP for their product against the comparator product Moxiget Tablet of Getz Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510711/008/2021		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB-01/M400	TB-02/M400	TB-03/M400
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	24-02-2022	24-02-2022	24-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 02-09-2020 based on the inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 20-12-2021 specifying purchase of 8Kg moxifloxacin hydrochloride.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures	Submission of data in section 3.2.S.4.1 as per DRAP guideline which specifies that copies of drug substance specification and analytical procedure used for routine testing of drug substance by both drug substance and drug product manufacturer is provided.

	used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
2.	Provide verification studies of drug substance from drug product manufacturer.	Verification study of drug substance for drug product manufacturer are attached.
3.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number 00510711/008/2021 from both API manufacturer as well as drug product manufacturer
4.	Justify why your formulation is qualitatively different from the innovator product.	We follow innovator formulation, only two different inactive like polyvinylpyroliodne K-30 use for binding of tablet, make the paste of PVP-30 in isopropylalcohol, this paste is used for binding purpose and silicon dioxide is used for powder flow from hopper to disc. Our product Moxip 400mg Tablet is stable after checking of 3rd month stability and 6th month stability studies. **The formulation of the firm is qualitatively different from the innovator's product.**
5.	Justify why you have not performed pharmaceutical equivalence and CDP studies against innovator product.	We have tried to find innovator product but we can not found so that is why we purchase product of national pharma and performed CDP and pharmaceutical equivalence against that product.
6.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
7.	Provide analytical method for the testing of drug product in section 3.2.P.5.2.	**Firm has not submitted analytical method for the testing of drug product**
8.	Justify why your analytical method for drug product is different from USP in terms of column and calculation formula.	**No response submitted by the firm.**
9.	Justify how same results of dissolution and assay test is received at 3rd month time point for accelerated and real time stability studies for Batch TB-01/M400.	By mistakenly we write same result, actual result are attached along with chromatoghram which are not same. **Firm has not submitted any new analytical record.**
10.	Justify the significant change in assay result i.e. from 106.91% to 99.49% in accelerated stability study for batch TB-01/M400.	**Significant change occur in assay result of accelerated study for batch TB-01-M400 is due to some technical issue in our accelerated stability chamber, now it is in good working condition and such kinds of issue will not be repeated.**
11.	Justify the significant change in assay result i.e. from 106.00% to 99.75% in accelerated stability study for batch TB-02/M400.	**Significant change occur in assay result of accelerated study for batch TB-02-M400 is due to some technical issue in our accelerated stability chamber, now it is in good working condition and such kinds of issue will not be repeated.**
12.	Justify the significant change in assay result i.e. from 106.79% to 98.77% in accelerated stability study for batch TB-03/M400.	**Significant change occur in assay result of accelerated study for batch TB-03-M400 is due to some technical issue in our accelerated stability chamber, now it is in good working condition and such kinds of issue will not be repeated.**

13.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 20-12-2021 specifying purchase of 8Kg moxifloxacin hydrochloride.

Decision: Deferred for following submissions:

- **Report of drug-excipient compatibility studies, since the qualitative compositions is different from the innovator's product.**
- **Complete results of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) studies against the innovator's product i.e. Avelox Tablet.**
- **Analytical method for testing of drug product.**
- **Scientific justification how same results of assay and dissolution test is received at 3rd month time point at both accelerated and real time stability studies.**
- **Explanation of the technical issues in the accelerated stability chambers which leads to significant change in the results along with submission of report of digital data logger of the relevant accelerated stability chamber to support the explanation.**
- **Submission of 7500/- fee for revision of specifications to USP as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

220.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12387: 04-07-2022
	Details of fee submitted	PKR 30,000/- : 27-06-2022
	The proposed proprietary name / brand name	**ZIPRO 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated contains: Ciprofloxacin (as HCl)..……250mg
	Pharmaceutical form of applied drug	Yellowish oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Novidat tablet by Sami

	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Novidat Tablet of Sami Pharmaceuticals. Firm has submitted results of CDP for their product against the comparator product Novidat Tablet of Sami Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	00510011/217/2021
Description of Pack (Container closure system)	Alu-alu blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB-01/Z250	TB-02/Z250	TB-03/Z250
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	23-02-2022	23-02-2022	23-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 02-09-2020 based on the inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 06-12-2021 specifying purchase of 25Kg ciprofloxacin hydrochloride.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify how drug substance manufactured by Pharmagen complies both USP as well as BP specs.	As ciprofloxacin are given in BP I-590 and also in USP NF43 volume I that is why pharmagen complies both USP as well as BP specification.
2.	Provide verification studies of drug substance from drug product manufacturer.	Verification study of drug substance for drug product manufacturer are provided.
3.	Provide stability study data of 3 batches of drug substance as per zone IV-A conditions, since the submitted real time stability data is only till 12 months.	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40oC ± 2oC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30oC ± 2oC / 65% ± 5% RH for 36 months.
4.	Justify why your formulation is qualitatively different from the innovator product.	Innovator used croscormilose sodium for disintegration purpose and we AKHSAH pharma used sodium starch glycolate for such purpose, both material are used as disintegrent in pharmaceuticals. Innovator used Povidone and we AKHSAH pharma used polyvinylpyrolidine K-30 for binding purpose both are same materials. Innovator used hypromellose, macrogyl 400 and titanium dioxide for coating purpose and we AKHSAH pharma used Newcoat white ready to used material which contain above three materials so both have same role. Our product Zipro 250mg tablet is stable after checking of 3rd month and 6th month stability studies.

		The formulation of the firm is qualitatively different from the innovator's product.
5.	Justify why you have not performed pharmaceutical equivalence and CDP studies against innovator product.	As innovator product was not available at that time in market so we performed pharmaceutical equivalence and CDP aginst Novidate 250mg tablets of Sami Pharma. Onward we used a register innovator product in Pakistan if exist.
6.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
7.	Provide analytical method for the testing of drug product in section 3.2.P.5.2.	Firm has submitted specifications of the finished product. **However, the calculation formula for assay testing is different from that specified in USP.**
8.	Justify why you are using UV method for testing drug product while USP recommends HPLC method.	We follow USP monograph for testing of drug product , according USP monograph assay of ciprofloxacin is on HPLC and dissolution on UV.
9.	The analytical method of assay test of drug product submitted in verification studies is different from USP in terms of column, injection volume and calculation formula. Justification is required in this regard.	The chromatoghrapic condition written in verification studies are mistakenly type, we must follow conditions and calculation of assay and dissolution according to USP monograph onward.
10.	The retention time of the ciprofloxacin peak during stability studies varied from 2.09 minuts to over 5 minutes. Justification is required in this regard.	Due to column efficiency it was occuered, now we arranged recommend columns for each product and such situation will not be repeated in onward. **The firm have changed the column.**
11.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 06-12-2021 specifying purchase of 25Kg ciprofloxacin hydrochloride.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **For commerical batches, manufacturer shall apply the actual potency determined by drug substance analysis for the calculation of fill weight of Esomeprazole pellets per capsule.**
- **Registration Board further decided that registration letter shall be issued upon submission of following:**

a. Results of Comparative Dissolution Profile (CDP) against the innovator's product.

b. Performance of dissolution test as per USP monograph at next time point of Long term stability studies.

c. Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

221.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12387: 21-05-2022
	Details of fee submitted	PKR 30,000/- : 12-05-2022
	The proposed proprietary name / brand name	**ZIPRO 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated contains: Ciprofloxacin (as HCl)..……500mg
	Pharmaceutical form of applied drug	Yellowish oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Novidat tablet by Sami
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Novidat Tablet of Sami Pharmaceuticals. Firm has submitted results of CDP for their product against the comparator product Novidat Tablet of Sami Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/217/2021		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB-01/Z500	TB-02/Z500	TB-03/Z500
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	28-01-2022	28-01-2022	28-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 02-09-2020 based on the inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 06-12-2021 specifying purchase of 25Kg ciprofloxacin hydrochloride.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify how drug substance manufactured by Pharmagen complies both USP as well as BP specs.	As ciprofloxacin are given in BP I-590 and also in USP NF43 volume I that is why pharmagen complies both USP as well as BP specification.
2.	Provide verification studies of drug substance from drug product manufacturer.	Verification study of drug substance for drug product manufacturer are provided.
3.	Provide stability study data of 3 batches of drug substance as per zone IV-A conditions, since the submitted real time stability data is only till 12 months.	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
4.	Justify why your formulation is qualitatively different from the innovator product.	Innovator used croscormilose sodium for disintegration purpose and we AKHSAH pharma used sodium starch glycolate for such purpose, both material are used as disintegrent in pharmaceuticals. Innovator used Povidone and we AKHSAH pharma used polyvinylpyrolidine K-30 for binding purpose both are same materials. Innovator used hypromellose, macrogyl 400 and titanium dioxide for coating purpose and we AKHSAH pharma used Newcoat white ready to used material which contain above three materials so both have same role. Our product Zipro 250mg tablet is stable after checking of 3rd month and 6th month stability studies. **The formulation of the firm is qualitatively different from the innovator's product.**
5.	Justify why you have not performed pharmaceutical equivalence and CDP studies against innovator product.	As innovator product was not available at that time in market so we performed pharmaceutical equivalence and CDP aginst Novidate 250mg tablets of Sami Pharma. Onward we used a register innovator product in Pakistan if exist.
6.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
7.	Ciprofloxacin 250mg tablet shows more than 80% release in 30 minutes in acidic medium, while Ciprofloxacin 500mg tablet shows 6.07% release in 120 minutes. Justification is required in this regard.	Refrence sample released 5.41% and our sample zipro 500mg tablet release 6.07% in 120minutes in acidic medium is the average values of comparison. Onward we performed comparative dissolution profile studies for each tablet individually as per DRAP guideline as well as FDA guideline. **Firm has not justified this significant difference in drug release.**
8.	Provide analytical method for the testing of drug product in section 3.2.P.5.2.	Firm has submitted specifications of the finished product.

		However, the calculation formula for assay testing is different from that specified in USP.
9.	Justify why you are using UV method for testing drug product while USP recommends HPLC method.	We follow USP monograph for testing of drug product, according USP monograph assay of ciprofloxacin is on HPLC and dissolution on UV.
10.	The analytical method of assay test of drug product submitted in verification studies is different from USP in terms of column, injection volume and calculation formula. Justification is required in this regard.	The chromatoghrapic condition written in verification studies are mistakenly type, we must follow conditions and calculation of assay and dissolution according to USP monograph onward.
11.	The retention time of the ciprofloxacin peak during stability studies varied from 2.09 minuts to over 9 minutes. Justification is required in this regard.	Due to column efficiency it was occuered, now we arranged recommend columns for each product and such situation will not be repeated in onward. **The firm have changed the column.**
12.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 06-12-2021 specifying purchase of 25Kg ciprofloxacin hydrochloride.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **For commerical batches, manufacturer shall apply the actual potency determined by drug substance analysis for the calculation of fill weight of Esomeprazole pellets per capsule.**
- **Registration letter shall be issued upon submission of following documents:**
    a. **Results of Comparative Dissolution Profile (CDP) against the innovator's product.**
    b. **Performance of dissolution test as per USP monograph at next time point of Long term stability studies.**
    c. **Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

222.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 19522: 04-07-2022
	Details of fee submitted	PKR 30,000/- : 27-06-2022
	The proposed proprietary name / brand name	**ZIPRO 750mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated contains: Ciprofloxacin (as HCl)..……750mg
	Pharmaceutical form of applied drug	Yellowish oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Hiflox tablet by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Hiflox Tablet of Hilton Pharmaceuticals.

		Firm has submitted results of CDP for their product against the comparator product Hiflox Tablet of Hilton Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/217/2021		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB-01/Z750	TB-02/Z750	TB-03/Z750
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	23-02-2022	23-02-2022	23-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 02-09-2020 based on the inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 06-12-2021 specifying purchase of 25Kg ciprofloxacin hydrochloride.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify how drug substance manufactured by Pharmagen complies both USP as well as BP specs.	As ciprofloxacin are given in BP I-590 and also in USP NF43 volume I that is why pharmagen complies both USP as well as BP specification.
2.	Provide verification studies of drug substance from drug product manufacturer.	Verification study of drug substance for drug product manufacturer are provided.

3.	Provide stability study data of 3 batches of drug substance as per zone IV-A conditions, since the submitted real time stability data is only till 12 months.	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
4.	Justify why your formulation is qualitatively different from the innovator product.	Innovator used croscormilose sodium for disintegration purpose and we AKHSAH pharma used sodium starch glycolate for such purpose, both material are used as disintegrent in pharmaceuticals. Innovator used Povidone and we AKHSAH pharma used polyvinylpyrolidine K-30 for binding purpose both are same materials. Innovator used hypromellose, macrogyl 400 and titanium dioxide for coating purpose and we AKHSAH pharma used Newcoat white ready to used material which contain above three materials so both have same role. Our product Zipro 250mg tablet is stable after checking of 3rd month and 6th month stability studies. **The formulation of the firm is qualitatively different from the innovator's product.**
5.	Justify why you have not performed pharmaceutical equivalence and CDP studies against innovator product.	As innovator product was not available at that time in market so we performed pharmaceutical equivalence and CDP aginst Novidate 250mg tablets of Sami Pharma. Onward we used a register innovator product in Pakistan if exist.
6.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
7.	Provide analytical method for the testing of drug product in section 3.2.P.5.2.	Firm has submitted specifications of the finished product. **However, the calculation formula for assay testing is different from that specified in USP.**
8.	Justify why you are using UV method for testing drug product while USP recommends HPLC method.	We follow USP monograph for testing of drug product, according USP monograph assay of ciprofloxacin is on HPLC and dissolution on UV.
9.	The analytical method of assay test of drug product submitted in verification studies is different from USP in terms of column, injection volume and calculation formula. Justification is required in this regard.	The chromatoghrapic condition written in verification studies are mistakenly type, we must follow conditions and calculation of assay and dissolution according to USP monograph onward.
10.	Provide analytical method for the testing of drug product in section 3.2.P.5.2.	Firm has submitted specifications of the finished product. **However, the calculation formula for assay testing is different from that specified in USP.**
11.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 06-12-2021 specifying purchase of 25Kg ciprofloxacin hydrochloride.

Decision: Approved.

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

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **For commerical batches, manufacturer shall apply the actual potency determined by drug substance analysis for the calculation of fill weight of Esomeprazole pellets per capsule.**
- **Registration letter shall be issued upon submission of following documents:**
  a. **Results of Comparative Dissolution Profile (CDP) against the innovator's product.**
  b. **Performance of dissolution test as per USP monograph at next time point of Long term stability studies.**
  c. **Fee of Rs. 7500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Case No. 02: M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Swabi.

Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section:
1. Liquid Injectable Infusion (SVP) LDPE (General)
2. Liquid Injectable Infusion (LVP) LDPE (General)

Now the firm has submitted following applications as per the details mentioned in the table below:

Name of Section	No of molecules	No of products
Liquid Injectable Infusion (SVP) LDPE (General)	01	03
Liquid Injectable Infusion (LVP) LDPE (General)	03	08

Liquid Injectable Infusion (SVP) LDPE (General): 01 Molecules / 03 Products

223.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10874: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 18-04-2022
	The proposed proprietary name / brand name	SAFE-INJECT 5ml

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Water for injection….5ml
	Pharmaceutical form of applied drug	Clear, colourless, odourless, and tasteless liquid filled in LDPE ampoule
	Pharmacotherapeutic Group of (API)	Solvent
	Reference to Finished product specifications	BP
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Water for Injection by M/s Otsuka Pakistan Ltd.
	Name and address of API manufacturer.	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data of drug substance related to nomenclature, structure, general properties, solubilities, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification and container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	NA
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Water for Injection by M/s Otsuka Pakistan Ltd.
	Analytical method validation/verification of product	NA

STABILITY STUDY DATA	
Manufacturer of API	NA
API Lot No.	NA
Description of Pack (Container closure system)	Low Density Polyethylene ampoule
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-001	T-001
Batch Size	100 liters	100 liters	100 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	12-01-2022	12-01-2022	12-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	NA
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide analytical method for water for injection in bulk in section 3.2.S.4.2, since the submitted method is not as per latest edition of BP monograph.	We have submitted the method for water for injection in bulk in section 3.2.S.4.2 that we have considered Pharmacopeia latest edition BP 2022.
2.	Justify why validation of analytical procedure of drug substance and drug product is not performed	The testing of drug substance or drug product do not involve any analytical testing like HPLC or UV analysis. The testing only involves Impurities, pH, conductivity, microbiological sterility & Endotoxin etc which only requires a calibrated equipment and does not require performing validation or verification studies.
3.	Provide details about the container closure system in which water for injection in bulk will be stored.	The container closure system in which water for injection in bulk will be stored in stainless steel container (316L).
4.	Justify why you have mentioned "not applicable" against the stability studies of drug substance in section 3.2.S.7.	Not applicable since it is explained in we have submitted that as Distilled water Manufacturing facilities are in-house.
5.	Define the maximum time period for which the bulk water for injection (drug substance) can be stored before filling in ampoule.	We use freshly prepared Distilled water just before batch manufacturing. We will not store Distilled water more than 2 hours.
6.	Justify why the test of residue on evaporation, Particulate contamination: sub-visible particles and sterility is not performed in pharmaceutical evaluation although these tests are specified in BP monograph.	We are performing these test regularly &will continuously in future also. Residue on evaporation Maximum 4 mg (0.004 per cent) for containers with a nominalvolume of 10 mL or less; maximum 3 mg

		(0.003 per cent) for containers with a nominalvolume greater than 10 rnL Evaporate 100 mL to dryness on a water-bath and dry in an oven at 100-105 ·C. Particulate contamination: sub-visible particles (2.9.19) It complies with test A or test B, as appropriate. Sterility (2.6.1)
7.	Justify why the test of residue on evaporation and Particulate contamination: sub-visible particles is not included in your drug product specifications although these tests are specified in BP monograph.	We are performing these test regularly &will continuously in future also. Residue on evaporation Maximum 4 mg (0.004 per cent) for containers with a nominalvolume of 10 mL or less; maximum 3 mg (0.003 per cent) for containers with a nominalvolume greater than 10 rnL Evaporate 100 mL to dryness on a water-bath and dry in an oven at 100-105 ·C. Particulate contamination: sub-visible particles (2.9.19) It complies with test A or test B, as appropriate. Sterility (2.6.1)
8.	Provide analytical method for sterile water for injection in section 3.2.P.5.2, since the submitted method is not as per latest edition of BP monograph.	Firm has submitted detailed analytical method for water for injection as per BP.
9.	Justify how initial stability study results are different for accelerated and real time stability studies.	We are submitted initial stability study result are different accelerated and real time stability studies. But minor change in results according to 2 different analyst testing variation. But results are in range according to BP. Then we have change the practice. We performed the test of same batch on zero month time point.

Discussion: Registration Board was apprised of the inspection report of the firm for the purpose of grant of new license. The report specifies the following facilities:

Formulations	Pharmacological category	Activities
Small volume Parenterals (SVP)	General	Solution preparation tanks (02 in number) with mixers, Circulation Pump, Filtration Assembly, Ampoule Rommelage Blow Fill Seal Machine.
Large volume Parenterals (LVP)	General	Hot runner molds (02 in number), injection molding machine for pre-form, Euro-cap mold, injection molding machine, for Weuro-cap, Solution preparation tanks (02 in number) with mixers, Circulation Pump, Filtration Assembly, Bottle Blowing machine, Bottle Filling Machine, Bottle Capping Machine.

Decision: Approved with change in brand name.

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

224.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10875: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 18-04-2022
	The proposed proprietary name / brand name	SAFE-INJECT 10ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Water for injection….10ml
	Pharmaceutical form of applied drug	Clear, colourless, odourless, and tasteless liquid filled in LDPE ampoule
	Pharmacotherapeutic Group of (API)	Solvent
	Reference to Finished product specifications	BP
	Proposed Pack size	10ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Water for Injection by M/s Otsuka Pakistan Ltd.
	Name and address of API manufacturer.	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data of drug substance related to nomenclature, structure, general properties, solubilities, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification and container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	NA
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process

		and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in BP for their product against the reference product Water for Injection by M/s Otsuka Pakistan Ltd.
	Analytical method validation/verification of product	NA

STABILITY STUDY DATA			
Manufacturer of API	NA		
API Lot No.	NA		
Description of Pack (Container closure system)	Low Density Polyethylene ampoule		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-001	T-001
Batch Size	100 liters	100 liters	100 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	13-01-2022	13-01-2022	13-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	NA
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide analytical method for water for injection in bulk in section 3.2.S.4.2, since the submitted method is not as per latest edition of BP monograph.	We have submitted the method for water for injection in bulk in section 3.2.S.4.2 that we have considered Pharmacopeia latest edition BP 2022.

2.	Justify why validation of analytical procedure of drug substance and drug product is not performed	The testing of drug substance or drug product do not involve any analytical testing like HPLC or UV analysis. The testing only involves Impurities, pH, conductivity, microbiological sterility & Endotoxin etc which only requires a calibrated equipment and does not require performing validation or verification studies.
3.	Provide details about the container closure system in which water for injection in bulk will be stored.	The container closure system in which water for injection in bulk will be stored in stainless steel container (316L).
4.	Justify why you have mentioned "not applicable" against the stability studies of drug substance in section 3.2.S.7.	Not applicable since it is explained in we have submitted that as Distilled water Manufacturing facilities are in-house.
5.	Define the maximum time period for which the bulk water for injection (drug substance) can be stored before filling in ampoule.	We use freshly prepared Distilled water just before batch manufacturing. We will not store Distilled water more than 2 hours.
6.	Justify why the test of residue on evaporation, Particulate contamination: sub-visible particles and sterility is not performed in pharmaceutical evaluation although these tests are specified in BP monograph.	We are performing these test regularly &will continuously in future also. Residue on evaporation Maximum 4 mg (0.004 per cent) for containers with a nominalvolume of 10 mL or less; maximum 3 mg (0.003 per cent) for containers with a nominalvolume greater than 10 rnL Evaporate 100 mL to dryness on a water-bath and dry in an oven at 100-105 ·C. Particulate contamination: sub-visible particles (2.9.19) It complies with test A or test B, as appropriate. Sterility (2.6.1)
7.	Justify why the test of residue on evaporation and Particulate contamination: sub-visible particles is not included in your drug product specifications although these tests are specified in BP monograph.	We are performing these test regularly &will continuously in future also. Residue on evaporation Maximum 4 mg (0.004 per cent) for containers with a nominalvolume of 10 mL or less; maximum 3 mg (0.003 per cent) for containers with a nominalvolume greater than 10 rnL Evaporate 100 mL to dryness on a water-bath and dry in an oven at 100-105 ·C. Particulate contamination: sub-visible particles (2.9.19) It complies with test A or test B, as appropriate. Sterility (2.6.1)
8.	Provide analytical method for sterile water for injection in section 3.2.P.5.2, since the submitted method is not as per latest edition of BP monograph.	Firm has submitted detailed analytical method for water for injection as per BP.
9.	Justify how initial stability study results are different for accelerated and real time stability studies.	We are submitted initial stability study result are different accelerated and real time stability studies. But minor change in results according to 2 different analyst testing variation. But results are in range according to BP. Then we have change the practice. We performed the test of same batch on zero month time point.

Discussion: Registration Board was apprised of the inspection report of the firm for the purpose of grant of new license. The report specifies the following facilities:

Formulations	Pharmacological category	Activities

Small volume Parenterals (SVP)	General	Solution preparation tanks (02 in number) with mixers, Circulation Pump, Filtration Assembly, Ampoule Rommelage Blow Fill Seal Machine.
Large volume Parenterals (LVP)	General	Hot runner molds (02 in number), injection molding machine for pre-form, Euro-cap mold, injection molding machine, for Weuro-cap, Solution preparation tanks (02 in number) with mixers, Circulation Pump, Filtration Assembly, Bottle Blowing machine, Bottle Filling Machine, Bottle Capping Machine.

Decision: Approved with change in brand name.

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

225.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10876: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 18-04-2022
	The proposed proprietary name / brand name	SAFE-INJECT 20ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Water for injection….20ml
	Pharmaceutical form of applied drug	Clear, colourless, odourless, and tasteless liquid filled in LDPE ampoule
	Pharmacotherapeutic Group of (API)	Solvent
	Reference to Finished product specifications	BP
	Proposed Pack size	20ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Water for Injection by M/s Otsuka Pakistan Ltd.

	Name and address of API manufacturer.	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data of drug substance related to nomenclature, structure, general properties, solubilities, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification and container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	NA
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in BP for their product against the reference product Water for Injection by M/s Otsuka Pakistan Ltd.
	Analytical method validation/verification of product	NA

STABILITY STUDY DATA			
Manufacturer of API	NA		
API Lot No.	NA		
Description of Pack (Container closure system)	Low Density Polyethylene ampoule		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-001	T-001
Batch Size	100 liters	100 liters	100 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	14-01-2022	14-01-2022	14-01-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	NA
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide analytical method for water for injection in bulk in section 3.2.S.4.2, since the submitted method is not as per latest edition of BP monograph.	We have submitted the method for water for injection in bulk in section 3.2.S.4.2 that we have considered Pharmacopeia latest edition BP 2022.
2.	Justify why validation of analytical procedure of drug substance and drug product is not performed	The testing of drug substance or drug product do not involve any analytical testing like HPLC or UV analysis. The testing only involves Impurities, pH, conductivity, microbiological sterility & Endotoxin etc which only requires a calibrated equipment and does not require performing validation or verification studies.
3.	Provide details about the container closure system in which water for injection in bulk will be stored.	The container closure system in which water for injection in bulk will be stored in stainless steel container (316L).
4.	Justify why you have mentioned "not applicable" against the stability studies of drug substance in section 3.2.S.7.	Not applicable since it is explained in we have submitted that as Distilled water Manufacturing facilities are in-house.
5.	Define the maximum time period for which the bulk water for injection (drug substance) can be stored before filling in ampoule.	We use freshly prepared Distilled water just before batch manufacturing. We will not store Distilled water more than 2 hours.
6.	Justify why the test of residue on evaporation, Particulate contamination: sub-visible particles and sterility is not performed in pharmaceutical evaluation although these tests are specified in BP monograph.	We are performing these test regularly &will continuously in future also. Residue on evaporation Maximum 4 mg (0.004 per cent) for containers with a nominalvolume of 10 mL or less; maximum 3 mg (0.003 per cent) for containers with a nominalvolume greater than 10 rnL Evaporate 100 mL to dryness on a water-bath and dry in an oven at 100-105 ·C. Particulate contamination: sub-visible particles (2.9.19) It complies with test A or test B, as appropriate. Sterility (2.6.1)
7.	Justify why the test of residue on evaporation and Particulate contamination: sub-visible particles is not included in your drug product specifications although these tests are specified in BP monograph.	We are performing these test regularly &will continuously in future also. Residue on evaporation Maximum 4 mg (0.004 per cent) for containers with a nominalvolume of 10 mL or less; maximum 3 mg (0.003 per cent)

		for containers with a nominalvolume greater than 10 rnL Evaporate 100 mL to dryness on a water-bath and dry in an oven at 100-105 ·C. Particulate contamination: sub-visible particles (2.9.19) It complies with test A or test B, as appropriate. Sterility (2.6.1)
8.	Provide analytical method for sterile water for injection in section 3.2.P.5.2, since the submitted method is not as per latest edition of BP monograph.	Firm has submitted detailed analytical method for water for injection as per BP.
9.	Justify how initial stability study results are different for accelerated and real time stability studies.	We are submitted initial stability study result are different accelerated and real time stability studies. But minor change in results according to 2 different analyst testing variation. But results are in range according to BP. Then we have change the practice. We performed the test of same batch on zero month time point.

Discussion: Registration Board was apprised of the inspection report of the firm for the purpose of grant of new license. The report specifies the following facilities:

Formulations	Pharmacological category	Activities
Small volume Parenterals (SVP)	General	Solution preparation tanks (02 in number) with mixers, Circulation Pump, Filtration Assembly, Ampoule Rommelage Blow Fill Seal Machine.
Large volume Parenterals (LVP)	General	Hot runner molds (02 in number), injection molding machine for pre-form, Euro-cap mold, injection molding machine, for Weuro-cap, Solution preparation tanks (02 in number) with mixers, Circulation Pump, Filtration Assembly, Bottle Blowing machine, Bottle Filling Machine, Bottle Capping Machine.

Decision: Approved with change in brand name.

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

Liquid Injectable Infusion (LVP) LDPE (General): 03 Molecules / 08 Products

226.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11603: 13-05-2022
	Details of fee submitted	PKR 30,000/- : 13-05-2022
	The proposed proprietary name / brand name	SAFESOL-NS IV Infusion 100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.9gm
	Pharmaceutical form of applied drug	Clear, colourless, odourless, saline solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Medisol NS 0.9% IV Infusion 100ml by M/s Medipak Limited.
	Name and address of API manufacturer.	M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests against the reference product "Plasaline 0.9% sodium chloride IV Infusion" by M/s Otsuka Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.		
API Lot No.	21104		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	250 liters	250 liters	250 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	21-01-2022	21-01-2022	21-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). Firm has submitted copy of License to import on Form 6 dated 03-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Specify the fill volume of applied product, since you have mentioned 100ml on covering	The fill volume in section 1.5.3 is corrected SAFESOL-NS infusion 100ml in place of 500ml.

	letter and fee challan while 500ml in section 1.5.3.	
2.	Specify finished product specification in section 1.5.6 along with submission of applicable fee.	Finished product specification in section 1.5.6 according to BP 2022. Firm has not submitted fee for revision of specifications.
3.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
4.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report f verification studies of the analytical method of drug substance performed by drug product manufacturer.
5.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 21104 from both API manufacturer as well as drug product manufacturer.
6.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
7.	Provide actual signed data sheets for three batches of the drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 60 months.
8.	Clarify the specifications and analytical method used to perform pharmaceutical equivalence studies.	Firm has submitted specifications and analytical method as per BP used to perform pharmaceutical equivalence studies.
9.	Justify the finished product specification, because your specifications and analytical procedures are different from both BP as well as USP monograph.	Firm has submitted specifications as per BP monograph. However firm has not submitted any fee for revision of specs.
10.	Justify your pH range acceptance criteria because this range is different from that specified in any official monograph as well as reference product.	Firm has submitted that we will follow BP specificatiosn for pH as well.
11.	Justify the in house specifications on which you have performed validation studies.	We are the following BP monograph but performed completely analytical method validation.
12.	Provide stability study data of three batches, since stability data of only 1 batch is submitted.	Firm has submitted stability data sheets for three batches.
13.	You have specified that drug substance manufacturer is M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China while the commercial invoice is from Zhejiang Top Hankook Biopharm Co. Ltd. Justification is required in this regard.	M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China Is the manufacturing company. While Zhejiang Top Hankook Biopharm Co. Ltd china Is the Exporter trader.
14.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	firm has single facilities to manufacture the Simple caps to seals the bottles through sealing machine.

		Firm has not specified whether they are using Eurocap or not.
15.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
16.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss was submitted.
	Justify why you have not perfoemed test of water loss during the stability studies.	Firm has submitted that they have performed additional water loss study as per ICH guidelines and the data for water loss was submitted.
17.	The BMR shows that manufacturing of batches started on 21-01-2022, and in your stability data sheets you have specified that stability studies was initiated on 21-01-2022. Justification is required in this regard.	The firm has manufactured the All batches (T-001/T-002/T-003) for stability studies only. Firm has not submitted any justification against this query.
18.	Describe the minimum and maximum filling capacity of the manufacturing and filling facility.	Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine. No. Made Capacity Pac Size Machine

Machine	Made	Capacity	Pack Size
simple Cap Welding Machine	ISBM CHINA	50,000 Bottle/day	100 mL/ 500mL / 1000mL

Decision: Approved with change in brand name.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will specify whether the product is with Eurocap or without before issuance of Registration Letter.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

227.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11604: 13-05-2022
	Details of fee submitted	PKR 30,000/- : 13-05-2022
	The proposed proprietary name / brand name	SAFESOL-NS IV Infusion 500ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.9gm
	Pharmaceutical form of applied drug	Clear, colourless, odourless, saline solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Medisol NS 0.9% IV Infusion 100ml by M/s Medipak Limited.
	Name and address of API manufacturer.	M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests against the reference product "Plasaline 0.9% sodium chloride IV Infusion" by M/s Otsuka Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.		
API Lot No.	21104		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	250 liters	250 liters	250 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	22-01-2022	22-01-2022	22-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). Firm has submitted copy of License to import on Form 6 dated 03-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Specify the fill volume of applied product, since you have mentioned 100ml on covering letter and fee challan while 500ml in section 1.5.3.	The fill volume in section 1.5.3 is corrected SAFESOL-NS infusion 100ml in place of 500ml.
2.	Specify finished product specification in section 1.5.6 along with submission of applicable fee.	Finished product specification in section 1.5.6 according to BP 2022. Firm has not submitted fee for revision of specifications.
3.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
4.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report f verification studies of the analytical method of drug substance performed by drug product manufacturer.
5.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 21104 from both API manufacturer as well as drug product manufacturer.
6.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
7.	Provide actual signed data sheets for three batches of the drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 60 months.
8.	Clarify the specifications and analytical method used to perform pharmaceutical equivalence studies.	Firm has submitted specifications and analytical method as per BP used to perform pharmaceutical equivalence studies.
9.	Justify the finished product specification, because your specifications and analytical procedures are different from both BP as well as USP monograph.	Firm has submitted specifications as per BP monograph. However firm has not submitted any fee for revision of specs.
10.	Justify your pH range acceptance criteria because this range is different from that specified in any official monograph as well as reference product.	Firm has submitted that we will follow BP specificatiosn for pH as well.
11.	Justify the in house specifications on which you have performed validation studies.	We are the following BP monograph but performed completely analytical method validation.
12.	Provide stability study data of three batches, since stability data of only 1 batch is submitted.	Firm has submitted stability data sheets for three batches.

<table>
<tr><td>13.</td><td>You have specified that drug substance manufacturer is M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China while the commercial invoice is from Zhejiang Top Hankook Biopharm Co. Ltd. Justification is required in this regard.</td><td>M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China Is the manufacturing company. While Zhejiang Top Hankook Biopharm Co. Ltd china Is the Exporter trader.</td></tr>
<tr><td>14.</td><td>Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).</td><td>firm has single facilities to manufacture the
Simple caps to seals the bottles through sealing machine.
Firm has not specified whether they are using Eurocap or not.</td></tr>
<tr><td>15.</td><td>Provide details regarding the method of sterilization of the drug product.</td><td>Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.</td></tr>
<tr><td>16.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td></td><td>Justify why you have not perfoemed test of water loss during the stability studies.</td><td>Firm has submitted that they have performed additional water loss study as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td>17.</td><td>The BMR shows that manufacturing of batches started on 22-01-2022, and in your stability data sheets you have specified that stability studies was initiated on 22-01-2022. Justification is required in this regard.</td><td>The firm has manufactured the All batches (T-001/T-002/T-003) for stability studies only.

Firm has not submitted any justification against this query.</td></tr>
<tr><td>18.</td><td>Describe the minimum and maximum filling capacity of the manufacturing and filling facility.</td><td>Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine.
No. Made Capacity Pac Size Machine
<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table></td></tr>
</table>

Decision: Approved with change in brand name.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will specify whether the product is with Eurocap or without before issuance of Registration Letter.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

228.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11605: 13-05-2022
	Details of fee submitted	PKR 30,000/- : 13-05-2022
	The proposed proprietary name / brand name	SAFESOL-NS IV Infusion 1000ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride…….0.9gm
	Pharmaceutical form of applied drug	Clear, colourless, odourless, saline solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Medisol NS 0.9% IV Infusion 100ml by M/s Medipak Limited.
	Name and address of API manufacturer.	M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests against the reference product "Plasaline 0.9% sodium chloride IV Infusion" by M/s Otsuka Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.		
API Lot No.	21104		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	250 liters	250 liters	250 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	24-01-2022	24-01-2022	24-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). Firm has submitted copy of License to import on Form 6 dated 03-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Specify the fill volume of applied product, since you have mentioned 100ml on covering letter and fee challan while 500ml in section 1.5.3.	The fill volume in section 1.5.3 is corrected SAFESOL-NS infusion 100ml in place of 500ml.
2.	Specify finished product specification in section 1.5.6 along with submission of applicable fee.	Finished product specification in section 1.5.6 according to BP 2022. Firm has not submitted fee for revision of specifications.
3.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
4.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report f verification studies of the analytical method of drug substance performed by drug product manufacturer.
5.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 21104 from both API manufacturer as well as drug product manufacturer.
6.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
7.	Provide actual signed data sheets for three batches of the drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 60 months.
8.	Clarify the specifications and analytical method used to perform pharmaceutical equivalence studies.	Firm has submitted specifications and analytical method as per BP used to perform pharmaceutical equivalence studies.
9.	Justify the finished product specification, because your specifications and analytical procedures are different from both BP as well as USP monograph.	Firm has submitted specifications as per BP monograph. However firm has not submitted any fee for revision of specs.

<table>
<tr><td>10.</td><td>Justify your pH range acceptance criteria because this range is different from that specified in any official monograph as well as reference product.</td><td>Firm has submitted that we will follow BP specificatiosn for pH as well.</td></tr>
<tr><td>11.</td><td>Justify the in house specifications on which you have performed validation studies.</td><td>We are the following BP monograph but performed completely analytical method validation.</td></tr>
<tr><td>12.</td><td>Provide stability study data of three batches, since stability data of only 1 batch is submitted.</td><td>Firm has submitted stability data sheets for three batches.</td></tr>
<tr><td>13.</td><td>You have specified that drug substance manufacturer is M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China while the commercial invoice is from Zhejiang Top Hankook Biopharm Co. Ltd. Justification is required in this regard.</td><td>M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China Is the manufacturing company. While Zhejiang Top Hankook Biopharm Co. Ltd china Is the Exporter trader.</td></tr>
<tr><td>14.</td><td>Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).</td><td>firm has single facilities to manufacture the
Simple caps to seals the bottles through sealing machine.
Firm has not specified whether they are using Eurocap or not.</td></tr>
<tr><td>15.</td><td>Provide details regarding the method of sterilization of the drug product.</td><td>Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.</td></tr>
<tr><td>16.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td></td><td>Justify why you have not perfoemed test of water loss during the stability studies.</td><td>Firm has submitted that they have performed additional water loss study as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td>17.</td><td>The BMR shows that manufacturing of batches started on 24-01-2022, and in your stability data sheets you have specified that stability studies was initiated on 24-01-2022. Justification is required in this regard..</td><td>The firm has manufactured the All batches (T-001/T-002/T-003) for stability studies only.

Firm has not submitted any justification against this query.</td></tr>
<tr><td>18.</td><td>Describe the minimum and maximum filling capacity of the manufacturing and filling facility.</td><td>Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine.
No. Made Capacity Pac Size Machine

<table>
<tr><th>Machine</th><th>Made</th><th>Capacity</th><th>Pack Size</th></tr>
<tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr>
</table>
</td></tr>
</table>

Decision: Approved with change in brand name.

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm will specify whether the product is with Eurocap or without before issuance of Registration Letter.** • **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
229.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10621: 26-04-2022
	Details of fee submitted	PKR 30,000/- : 23-04-2022
	The proposed proprietary name / brand name	SAFESOL-5 IV Infusion 100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Medisol 5% IV Infusion by M/s Medipak Limited
	Name and address of API manufacturer.	Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Pladex-5 IV Infusion by M/s Otsuka Pakistan Limited."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China.		
API Lot No.	202112028		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	10.5 liters	10.5 liters	10.5 liters
Manufacturing Date	01-2022	01-2022	01-2022

Date of Initiation	15-01-2022	15-01-2022	15-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20180787) issued by China Food and Drug Administration. The certificate is valid till 14-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to import on Form 6 dated 03-12-2021. Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide evidence of applied formulation as dextrose anhydrous in reference regulatory authorities.	Dextrose and glucose are used in the same meanings. Baxter UK manufacture glucose 5% From glucose monohydrate that means dextrose monohydrate; is utilized by Baxter UK which is same as dextrose anhydrous with one additional molecule of water and approved by US FDA.
2.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
3.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report f verification studies of the analytical method of drug substance performed by drug product manufacturer.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 202112028 from both API manufacturer as well as drug product manufacturer.
5.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
6.	Provide actual signed data sheets for three batches of the drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.

<table>
<tr><td></td><td>placed instead of being signed and stamped by drug substance manufacturer.</td><td></td></tr>
<tr><td>7.</td><td>The submitted specifications in section 3.2.P.5.1 contains test of physical appearance, pH, volume variation limit, identification and assay, while further tests are also specified in pharmaceutical equivalence and analytical procedures in section 3.2.P.5.2.</td><td>Firm has submitted specifications and analytical method as per BP used to perform pharmaceutical equivalence studies.</td></tr>
<tr><td>8.</td><td>Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.</td><td>Firm has submitted verification studies of the analytical method of drug product.</td></tr>
<tr><td>9.</td><td>Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).</td><td>Firm has both facilities of manufacturing the Simple caps & Eu ro cap.
Firm has not specified whether they are using Eurocap or not.</td></tr>
<tr><td>10.</td><td>Provide details regarding the method of sterilization of the drug product.</td><td>Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.</td></tr>
<tr><td>11.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td>12.</td><td>Justify why you have not perfoemed test of water loss during the stability studies.</td><td>Firm has submitted that they have performed additional water loss study as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td>13.</td><td>The BMR shows that manufacturing of batches started on 15-01-2022, and in your stability data sheets you have specified that stability studies was initiated on 15-01-2022. Justification is required in this regard.</td><td>The Product was found completely STERILE after 02 to 03 times B.E.T. Testing further the batches were completely manufactured for stability studies and sterility Process was done two times at 03 months and at 06 months That is why batches were transferred to stability chambers after complete testing and performing B.E.T. Testing. Two to three times.</td></tr>
<tr><td>14.</td><td>Describe the minimum and maximum filling capacity of the manufacturing and filling facility.</td><td>Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine.
No. Made Capacity Pac Size Machine
<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table></td></tr>
<tr><td>15.</td><td>Provide raw data sheet for calculation of results of stability studies at each month time point.</td><td>Firm has submitted raw data sheets for results of stability studies at each time point.</td></tr>
<tr><td>16.</td><td>Justify how results of initial stability studies are different at accelerated and real time conditions.</td><td>We have submitted initial stability result are different accelerated and real time stability studies. But minor change in results according to</td></tr>
</table>

		two different analysts testing variation. But results are in range according to BP. Then we have changed the practice. We performed the test of same batch on zero month time point.
17.	Submit evidence of import including copy of commercial invoice cleared by AD (I&E) DRAP for the import of dextrose batch number 202112028.	Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous.

Decision: Approved with change in brand name.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will specify whether the product is with Eurocap or without before issuance of Registration Letter.**

230.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10622: 26-04-2022
	Details of fee submitted	PKR 30,000/- : 23-04-2022
	The proposed proprietary name / brand name	SAFESOL-5 IV Infusion 500ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Medisol 5% IV Infusion by M/s Medipak Limited
	Name and address of API manufacturer.	Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Pladex-5 IV Infusion by M/s Otsuka Pakistan Limited."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China.
API Lot No.	202112028
Description of Pack (Container closure system)	Polypropylene
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	52.5 liters	52.5 liters	52.5 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	17-01-2022	17-01-2022	17-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20180787) issued by China Food and Drug Administration. The certificate is valid till 14-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to import on Form 6 dated 03-12-2021. Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide evidence of applied formulation as dextrose anhydrous in reference regulatory authorities.	Dextrose and glucose are used in the same meanings. Baxter UK manufacture glucose 5% From glucose monohydrate that means dextrose monohydrate; is utilized by Baxter UK which is same as dextrose anhydrous with one additional molecule of water and approved by US FDA.
2.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
3.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report f verification studies of the analytical method of drug substance performed by drug product manufacturer.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 202112028 from both API manufacturer as well as drug product manufacturer.
5.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.

<table>
<tr><td>6.</td><td>Provide actual signed data sheets for three batches of the drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.</td><td>Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.</td></tr>
<tr><td>7.</td><td>The submitted specifications in section 3.2.P.5.1 contains test of physical appearance, pH, volume variation limit, identification and assay, while further tests are also specified in pharmaceutical equivalence and analytical procedures in section 3.2.P.5.2.</td><td>Firm has submitted specifications and analytical method as per BP used to perform pharmaceutical equivalence studies.</td></tr>
<tr><td>8.</td><td>Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.</td><td>Firm has submitted verification studies of the analytical method of drug product.</td></tr>
<tr><td>9.</td><td>Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).</td><td>Firm has both facilities of manufacturing the Simple caps & Eu ro cap.
Firm has not specified whether they are using Eurocap or not.</td></tr>
<tr><td>10.</td><td>Provide details regarding the method of sterilization of the drug product.</td><td>Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.</td></tr>
<tr><td>11.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td>12.</td><td>Justify why you have not perfoemed test of water loss during the stability studies.</td><td>Firm has submitted that they have performed additional water loss study as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td>13.</td><td>The BMR shows that manufacturing of batches started on 17-01-2022, and in your stability data sheets you have specified that stability studies was initiated on 17-01-2022. Justification is required in this regard.</td><td>The Product was found completely STERILE after 02 to 03 times B.E.T. Testing further the batches were completely manufactured for stability studies and sterility Process was done two times at 03 months and at 06 months That is why batches were transferred to stability chambers after complete testing and performing B.E.T. Testing. Two to three times.</td></tr>
<tr><td>14.</td><td>Describe the minimum and maximum filling capacity of the manufacturing and filling facility.</td><td>Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine.
No. Made Capacity Pac Size Machine
<table>
<tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr>
<tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr>
</table></td></tr>
</table>

15.	Provide raw data sheet for calculation of results of stability studies at each month time point.	Firm has submitted raw data sheets for results of stability studies at each time point.
16.	Justify how results of initial stability studies are different at accelerated and real time conditions.	We have submitted initial stability result are different accelerated and real time stability studies. But minor change in results according to two different analysts testing variation. But results are in range according to BP. Then we have changed the practice. We performed the test of same batch on zero month time point.
17.	Submit evidence of import including copy of commercial invoice cleared by AD (I&E) DRAP for the import of dextrose batch number 202112028.	Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous.

Decision: Approved with change in brand name.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will specify whether the product is with Eurocap or without before issuance of Registration Letter.**

231.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10623: 26-04-2022
	Details of fee submitted	PKR 30,000/- : 23-04-2022
	The proposed proprietary name / brand name	SAFESOL-5 IV Infusion 1000ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm

	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Medisol 5% IV Infusion by M/s Medipak Limited
	Name and address of API manufacturer.	Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Pladex-5 IV Infusion by M/s Otsuka Pakistan Limited."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China.
API Lot No.	202112028

Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	105 liters	105 liters	105 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	18-01-2022	18-01-2022	18-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20180787) issued by China Food and Drug Administration. The certificate is valid till 14-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to import on Form 6 dated 03-12-2021. Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide evidence of applied formulation as dextrose anhydrous in reference regulatory authorities.	Dextrose and glucose are used in the same meanings. Baxter UK manufacture glucose 5% From glucose monohydrate that means dextrose monohydrate; is utilized by Baxter UK which is same as dextrose anhydrous with one additional molecule of water and approved by US FDA.
2.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
3.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report f verification studies of the analytical method of drug substance performed by drug product manufacturer.

4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 202112028 from both API manufacturer as well as drug product manufacturer.
5.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
6.	Provide actual signed data sheets for three batches of the drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.
7.	The submitted specifications in section 3.2.P.5.1 contains test of physical appearance, pH, volume variation limit, identification and assay, while further tests are also specified in pharmaceutical equivalence and analytical procedures in section 3.2.P.5.2.	Firm has submitted specifications and analytical method as per BP used to perform pharmaceutical equivalence studies.
8.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	Firm has submitted verification studies of the analytical method of drug product.
9.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Eu ro cap. Firm has not specified whether they are using Eurocap or not.
10.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
11.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss was submitted.
12.	Justify why you have not perfoemed test of water loss during the stability studies.	Firm has submitted that they have performed additional water loss study as per ICH guidelines and the data for water loss was submitted.
13.	The BMR shows that manufacturing of batches started on 18-01-2022, and in your stability data sheets you have specified that stability studies was initiated on 18-01-2022. Justification is required in this regard.	The Product was found completely STERILE after 02 to 03 times B.E.T. Testing further the batches were completely manufactured for stability studies and sterility Process was done two times at 03 months and at 06 months That is why batches were transferred to stability chambers after complete testing and performing B.E.T. Testing. Two to three times.
14.	Describe the minimum and maximum filling capacity of the manufacturing and filling facility.	Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine. No. Made Capacity Pac Size Machine

		<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table>
15.	Provide raw data sheet for calculation of results of stability studies at each month time point.	Firm has submitted raw data sheets for results of stability studies at each time point.
16.	Justify how results of initial stability studies are different at accelerated and real time conditions.	We have submitted initial stability result are different accelerated and real time stability studies. But minor change in results according to two different analysts testing variation. But results are in range according to BP. Then we have changed the practice. We performed the test of same batch on zero month time point.
17.	Submit evidence of import including copy of commercial invoice cleared by AD (I&E) DRAP for the import of dextrose batch number 202112028.	Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous.

Decision: Approved with change in brand name.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will specify whether the product is with Eurocap or without before issuance of Registration Letter.**

232.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10872: 29-04-2022

	Details of fee submitted	PKR 30,000/- : 29-04-2022
	The proposed proprietary name / brand name	SAFESOL-DS IV Infusion 500ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm Sodium Chloride…..0.9gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Pladexsal IV Infusion by M/s Otsuka
	Name and address of API manufacturer.	Glucose Anhydrous: Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China. Sodium Chloride: M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Glucose Anhydrous: Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months. Sodium Chloride: Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Pladexsal IV Infusion by M/s Otsuka Pakistan Limited."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Glucose Anhydrous: Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China. Sodium Chloride: M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.		
API Lot No.	Glucose Anhydrous: 202112028 Sodium Chloride: 21104		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	55 liters	55 liters	55 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	19-01-2022	19-01-2022	19-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Glucose Anhydrous: Firm has submitted copy of GMP certificate (No. SD20180787) issued by China Food and Drug Administration. The certificate is valid till 14-10-2023. Sodium Chloride: Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Glucose Anhydrous: Firm has submitted copy of License to import on Form 6 dated 03-12-2021. Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous. Sodium Chloride: Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). Firm has submitted copy of License to import on Form 6 dated 03-12-2021.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide reference of finished product specifications in module 1 along with submission of fee for revision of specifications.	Firm has submitted reference of finished product specifications as BP without submission of fee.
2.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
3.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report f verification studies of the analytical method of drug substance performed by drug product manufacturer.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 202112028 from both API manufacturer as well as drug product manufacturer.
5.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
6.	Provide actual signed data sheets for three batches of the drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.
7.	The submitted specifications in section 3.2.P.5.1 contains test of physical appearance, pH, volume variation limit, identification and assay, while further tests are also specified in pharmaceutical equivalence and analytical procedures in section 3.2.P.5.2.	Firm has submitted specifications and analytical method as per BP used to perform pharmaceutical equivalence studies.
8.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	Firm has submitted verification studies of the analytical method of drug product.
9.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Eu ro cap. Firm has not specified whether they are using Eurocap or not.
10.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in

<table>
<tr><td></td><td></td><td>Sterilization cycle. Details of sterilization process is provided by firm.</td></tr>
<tr><td>11.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td>12.</td><td>Justify why you have not perfoemed test of water loss during the stability studies.</td><td>Firm has submitted that they have performed additional water loss study as per ICH guidelines and the data for water loss was submitted.</td></tr>
<tr><td>13.</td><td>The BMR shows that manufacturing of batches started on 19-01-2022, and in your stability data sheets you have specified that stability studies was initiated on 19-01-2022. Justification is required in this regard.</td><td>The Product was found completely STERILE after 02 to 03 times B.E.T. Testing further the batches were completely manufactured for stability studies and sterility Process was done two times at 03 months and at 06 months That is why batches were transferred to stability chambers after complete testing and performing B.E.T. Testing. Two to three times.</td></tr>
<tr><td>14.</td><td>Describe the minimum and maximum filling capacity of the manufacturing and filling facility.</td><td>Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine.
No. Made Capacity Pac Size Machine
<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table></td></tr>
<tr><td>15.</td><td>Provide raw data sheet for calculation of results of stability studies at each month time point.</td><td>Firm has submitted raw data sheets for results of stability studies at each time point.</td></tr>
<tr><td>16.</td><td>Justify how results of initial stability studies are different at accelerated and real time conditions.</td><td>We have submitted initial stability result are different accelerated and real time stability studies. But minor change in results according to two different analysts testing variation. But results are in range according to BP.
Then we have changed the practice. We performed the test of same batch on zero month time point.</td></tr>
<tr><td>17.</td><td>Submit evidence of import including copy of commercial invoice cleared by AD (I&E) DRAP for the import of dextrose batch number 202112028.</td><td>Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous.</td></tr>
</table>

Decision: Approved with change in brand name.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will specify whether the product is with Eurocap or without before issuance of Registration Letter.**

• **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
233.	Name, address of Applicant / Marketing Authorization Holder	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10873: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 29-04-2022
	The proposed proprietary name / brand name	SAFESOL-DS IV Infusion 1000ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm Sodium Chloride…..0.9gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Pladexsal IV Infusion by M/s Otsuka
	Name and address of API manufacturer.	Glucose Anhydrous: Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China. Sodium Chloride: M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties,

		solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Glucose Anhydrous: Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months. Sodium Chloride: Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Pladexsal IV Infusion by M/s Otsuka Pakistan Limited."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Glucose Anhydrous: Weifang Shengtain Medicine Co Ltd. The east of Changda Road, Changle County, Weifang City, Shandong Province, PR China. Sodium Chloride: M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China.
API Lot No.	Glucose Anhydrous: 202112028 Sodium Chloride: 21104
Description of Pack (Container closure system)	Polypropylene
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	110 liters	110 liters	110 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	19-01-2022	19-01-2022	19-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Glucose Anhydrous: Firm has submitted copy of GMP certificate (No. SD20180787) issued by China Food and Drug Administration. The certificate is valid till 14-10-2023. Sodium Chloride: Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Glucose Anhydrous: Firm has submitted copy of License to import on Form 6 dated 03-12-2021. Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous. Sodium Chloride: Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). Firm has submitted copy of License to import on Form 6 dated 03-12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide reference of finished product specifications in module 1 along with submission of fee for revision of specifications.	Firm has submitted reference of finished product specifications as BP without submission of fee.
2.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.

3.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report f verification studies of the analytical method of drug substance performed by drug product manufacturer.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 202112028 from both API manufacturer as well as drug product manufacturer.
5.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
6.	Provide actual signed data sheets for three batches of the drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.
7.	The submitted specifications in section 3.2.P.5.1 contains test of physical appearance, pH, volume variation limit, identification and assay, while further tests are also specified in pharmaceutical equivalence and analytical procedures in section 3.2.P.5.2.	Firm has submitted specifications and analytical method as per BP used to perform pharmaceutical equivalence studies.
8.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	Firm has submitted verification studies of the analytical method of drug product.
9.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Eu ro cap. Firm has not specified whether they are using Eurocap or not.
10.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
11.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss was submitted.
12.	Justify why you have not perfoemed test of water loss during the stability studies.	Firm has submitted that they have performed additional water loss study as per ICH guidelines and the data for water loss was submitted.
13.	The BMR shows that manufacturing of batches started on 19-01-2022, and in your stability data sheets you have specified that stability studies was initiated on 19-01-2022. Justification is required in this regard.	The Product was found completely STERILE after 02 to 03 times B.E.T. Testing further the batches were completely manufactured for stability studies and sterility Process was done two times at 03 months and at 06 months That is why batches were transferred to stability chambers after complete testing and performing B.E.T. Testing. Two to three times.
14.	Describe the minimum and maximum filling capacity of the manufacturing and filling facility.	Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the

<table>
<tr><td></td><td></td><td>simple cap machine are provided below simple cap Machine.
No. Made Capacity Pac Size Machine
<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table></td></tr>
<tr><td>15.</td><td>Provide raw data sheet for calculation of results of stability studies at each month time point.</td><td>Firm has submitted raw data sheets for results of stability studies at each time point.</td></tr>
<tr><td>16.</td><td>Justify how results of initial stability studies are different at accelerated and real time conditions.</td><td>We have submitted initial stability result are different accelerated and real time stability studies. But minor change in results according to two different analysts testing variation. But results are in range according to BP.
Then we have changed the practice. We performed the test of same batch on zero month time point.</td></tr>
<tr><td>17.</td><td>Submit evidence of import including copy of commercial invoice cleared by AD (I&E) DRAP for the import of dextrose batch number 202112028.</td><td>Firm has submitted copy of commercial invoice cleared dated 04-01-2022. The invoice declare purchase of 50Kg Dextrose anhydrous.</td></tr>
</table>

Decision: Approved with change in brand name.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will specify whether the product is with Eurocap or without before issuance of Registration Letter.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Case No. 03: M/s Nagarsons Pharmaceuticals, Islamabad

Firm has submitted copy of Acknowledgment of receipt of application for grant of DML by way of formulation to M/s Nagarsons Pharmaceuticals dated 19-02-2021 from Secretary Central Licensing Board. The letter specifies that CLB in its 278th meeting held on 10th and 11th December 2020 has approved the grant of DML in the name of M/s Nagarsons Pharmaceuticals for following sections:

1. Tablet (General)
2. Tablet (Psychotropic)
3. Capsule (General)
4. Cream /ointment/Lotion/Gel

Now the firm has submitted following applications as per the details mentioned in the table below:

Name of Section	Previously considered		Newly applied		Total	
	No of molecules	No of products	No of molecules	No of products	No of molecules	No of products
Tablet (General)	04	07	01	01	05	08
Tablet (Psychotropic)	-	-	-	-	-	-
Capsule (General)	06	10	-	-	-	-

Cream /ointment/Lotion/Gel	-	-	-	-	-	-

Tablet (General) section: 01 Molecules / 01 Products		
234.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of Acknowledgment of receipt of application for grant of DML by way of formulation to M/s Nagarsons Pharmaceuticals dated 19-02-2021 from Secretary Central Licensing Board.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Acknowledgment of receipt of application for grant of DML by way of formulation to M/s Nagarsons Pharmaceuticals dated 19-02-2021 from Secretary Central Licensing Board. The letter specifies that CLB in its 278th meeting held on 10th and 11th December 2020 has approved the grant of DML in the name of M/s Nagarsons Pharmaceuticals for following sections: 1. Tablet (General) 2. Tablet (Psychotropic) 3. Capsule (General) 4. Cream /ointment/Lotion/Gel
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11699: 14-05-2022
	Details of fee submitted	PKR 30,000/-: 14-02-2022
	The proposed proprietary name / brand name	**PANTONAG 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet contains: Pantoprazole (as sodium sesquihydrate)……40mg
	Pharmaceutical form of applied drug	Enteric coated tablet
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**MHRA** Approved)
	For generic drugs (me-too status)	Protium Tablet 40mg of M/s Abbott Laboratories (Reg # 021039)
	Name and address of API manufacturer.	M/s Metrochem API Private imited Unit-I, Plot No. 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla,

		Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product i.e. Protium tablet of M/s Abbott Laboratories. Firm has submitted results of CDP for their product against the reference product i.e. Protium tablet of M/s Abbott Laboratories.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Metrochem API Private imited Unit-I, Plot No. 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Dist), Telangana State, India.
API Lot No.	PSS/2106041
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	26-09-2021	27-09-2021	28-09-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nagarsons Pharmaceutical is a new license facility hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 36935/TS/2020) issued by Drugs Control Administration Government of Telangana. The certificate is valid till 22-04-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 10Kg Pantoprazole sodium sesquihydrate cleared dated 23-08-2021. The invoice is cleared by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with UV spectra, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC systems are not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copy of specifications and analytical method of drug substance from both Drug substance & Drug Product manufacturer.
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	Firm has submitted verification studies of the drug substance performed by drug product manufacturer.
3.	Provide COA of reference standard / working standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of working standard of drug substance.
4.	Justify the comparative dissolution profile studies in which dissolution studies at phosphate buffer pH 6.8 are carried out only at 60 minutes.	**Firm has not submitted any response.**
5.	Specify the type of coating for the applied product since the innovator product specify seal coating and enteric coating.	**Firm has not submitted any response.**

6.	Specify the type of dissolution test for the drug product since USP specifies 4 different type of dissolution tests.	Firm has submitted that they have performed dissolution tests as per USP Test-2 Procedure.
7.	Provide raw data sheets for the analysis of results of assay and dissolution during stability studies.	Firm has submitted analytical record for dissolution and assay testing.
8.	Submit batch manufacturing record for three stability batches.	Firm has submitted copy of BMR of three stability batches.
9.	Submit valid GMP certificate of API manufacturer, since the submitted GMP certificate was valid till 22-04-2021.	Firm has submitted copy of License Retention Certificate dated 27-09-2019. The certificate specify that the license of M/s Metrochem to be retained till 29-09-2024.

Decision: Approved.

- **Registration letter will be issued upon submission of Comparative Dissolution Profile (CDP) studies against the innovator's product.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **For commercial batch manufacturing firm shall use coating materials with similar qualitative composition as per the innovator's product.**

Case No. 02 Registration applications of Form 5Fcases

a. Routine cases of local manufacturing

235.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 29-09-2020. The letter specifies following sections: • Tablet (General) (Revised) • Capsule (General) section (New) • R&D Laboratory (New) • Sachet (General) (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23832: 31-08-2021
	Details of fee submitted	PKR 30,000/-: 25-08-2021
	The proposed proprietary name / brand name	**DEXIMAX 30mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….30mg
	Pharmaceutical form of applied drug	Small white round enteric coated pellets encapsulated in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant capsule **USFDA** Approved.
	For generic drugs (me-too status)	Razodex Capsule by Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Dudex 30mg Capsule of Global Pharmaceuticals. Firm has submitted results of CDP for their product against Dudex 30mg Capsule of Global Pharmaceuticals.

	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	DLP723		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1/21	T2/21	T3/21
Batch Size	1600 Capsule	1600 Capsule	1600 Capsule
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	18-01-2021	18-01-2021	18-01-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to previous inspection report for their product Kaymax tablet containing diclofenac potassium 75mg tablet. The inspection was conducted on 10-03-2021 verification of product development data and confirmation of CAPA. The report was considered by the Board in its 307th meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 07-01-2021 specifying purchase of 2Kg dexlansoprazole pellets
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that their HPLC system is not 21 CFR compliant therefore the audit trail reports are not applicable.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug	Firm has submitted specifications and analytical method of drug substance from drug product manufacturer as well.

	substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	
2.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted that since the product contains ready to fill pellets therefore the validation studies of drug product can also be considered for the drug substance as well since both have same analytical method.
3.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number DLP723 from both API manufacturer as well as drug product manufacturer
4.	Justify why pharmaceutical equivalence and CDP studies were performed against Dudex Capsule of Global Pharmaceuticals instead of innovator's product.	Firm has submitted that since innovator product is not registered in Pakistan therefore they have used comparator product to perform testing as per DRAP guidelines.
5.	The innovator product is available as dual delayed release pellets in HPMC capsule shells while your product is in hard gelatin capsule shells. Justification is required in this regard.	The firm has submitted that we have performed product development and stability studies with hard gelatin capsule and found our product stable as well. Moreover, all comparator products in Pakistan are also available in hard gelatin capsule.
6.	Justify the dissolution testing of drug product using UV method.	We performed the assay on HPLC method according to drug substance manufacturer and performed dissolution on UV method. Our methods are as per the method of Vision Pharmaceuticals.
7.	Submit Batch Manufacturing Record of three batches.	Firm has submitted batch manufacturing record of three stability batches.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

236.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 29-09-2020. The letter specifies following sections: • Tablet (General) (Revised) • Capsule (General) section (New) • R&D Laboratory (New) • Sachet (General) (New)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23832: 31-08-2021
	Details of fee submitted	PKR 30,000/-: 25-08-2021
	The proposed proprietary name / brand name	**DEXIMAX 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….60mg
	Pharmaceutical form of applied drug	Small white round enteric coated pellets encapsulated in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant capsule **USFDA** Approved.
	For generic drugs (me-too status)	Razodex Capsule by Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Dudex 60mg Capsule of Global Pharmaceuticals. Firm has submitted results of CDP for their product against Dudex 60mg Capsule of Global Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	DLP723		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1/21	T2/21	T3/21
Batch Size	1600 Capsule	1600 Capsule	1600 Capsule
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	18-01-2021	18-01-2021	18-01-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to previous inspection report for their product Kaymax tablet containing diclofenac potassium 75mg tablet. The inspection was conducted on 10-03-2021 verification of product development data and confirmation of CAPA. The report was considered by the Board in its 307th meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 07-01-2021 specifying purchase of 2Kg dexlansoprazole pellets
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that their HPLC system is not 21 CFR compliant therefore the audit trail reports are not applicable.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications and analytical method of drug substance from drug product manufacturer as well.
2.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted that since the product contains ready to fill pellets therefore the validation studies of drug product can also be considered for the drug substance as well since both have same analytical method.
3.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number DLP723 from both API manufacturer as well as drug product manufacturer
4.	Justify why pharmaceutical equivalence and CDP studies were performed against Dudex Capsule of Global Pharmaceuticals instead of innovator's product.	Firm has submitted that since innovator product is not registered in Pakistan therefore they have used comparator product to perform testing as per DRAP guidelines.
5.	The innovator product is available as dual delayed release pellets in HPMC capsule shells while your product is in hard gelatin capsule shells. Justification is required in this regard.	The firm has submitted that we have performed product development and stability studies with hard gelatin capsule and found our product stable as well. Moreover, all comparator products in Pakistan are also available in hard gelatin capsule.
6.	Justify the dissolution testing of drug product using UV method.	We performed the assay on HPLC method according to drug substance manufacturer and performed dissolution on UV method. Our methods are as per the method of Vision Pharmaceuticals.
7.	Submit Batch Manufacturing Record of three batches.	Firm has submitted batch manufacturing record of three stability batches.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

237.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the firm	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25533: 14-09-2021
	Details of fee submitted	PKR 75,000/-: 06-09-2021
	The proposed proprietary name / brand name	**ARDCIL Injection 2.25g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium …….0.25g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Tazocin Injection of Pfizer.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.		
API Lot No.	SI/ PPT /00170120		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VZI038	VZI044	
Batch Size	20,374 vials	16,300 vials	
Manufacturing Date	03-2020	08-2020	
Date of Initiation	12-03-2020	29-08-2020	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 12/80-2Drug1-2019/3739 issued by Food and Drugs Administration Haryana dated 21-05-2019. The certificate is valid till 2 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 600Kg piperacillin sodium and tazobactam sodium sterile from Sterile India dated 19-02-2020. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	21 CFR status and audit trail reports on testing of product were not available.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Registration Board in its 291st meeting held on 02-04th September 2019 allowed contract manufacturing from M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for the following sections:

i. Dry powder Injectable (Penicillin)
ii. Liquid ampoule Injectable (General)
iii. Dry powder Lyophilized Injectable (General)
iv. Large Volume Vial Injectable (General)

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

238.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**English pharmaceuticals:** Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 17-08-2022. The certificate was issued based on the inspection dated 14-07-2022. The certificate specifies dry powder injection penicillin section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25534: 14-09-2021
	Details of fee submitted	PKR 75,000/-: 06-09-2021
	The proposed proprietary name / brand name	**ARDCIL Injection 4.5g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium …….0.5g
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals

	Name and address of API manufacturer.	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Tazocin Injection of Pfizer.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.
API Lot No.	SI/ PPT /00170120
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	VZI041	VZI042	
Batch Size	12,394 vials	12,394 vials	
Manufacturing Date	08-2020	08-2020	
Date of Initiation	15-08-2020	15-08-2020	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 12/80-2Drug1-2019/3739 issued by Food and Drugs Administration Haryana dated 21-05-2019. The certificate is valid till 2 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 600Kg piperacillin sodium and tazobactam sodium sterile from Sterile India dated 19-02-2020. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	21 CFR status and audit trail reports on testing of product were not available.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Registration Board in its 291st meeting held on 02-04th September 2019 allowed contract manufacturing from M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for the following sections:

i. Dry powder Injectable (Penicillin)
ii. Liquid ampoule Injectable (General)
iii. Dry powder Lyophilized Injectable (General)
iv. Large Volume Vial Injectable (General)

Decision: Approved.

- **Manufacture process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 03 Registration applications of Form-5 cases

a) Deferred cases

239.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals, 387-388, I-9, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Balance H Tablets 40 mg+12.5mg
	Composition	Each tablet contains: Telmisartan …..40mg Hydrochlorthiazide…..12.5mg
	Diary No. Date of R& I & fee	Dy. No. 10711; 02-10-2017; Rs.20,000/- (02-10-2017)
	Pharmacological Group	Antihypertensive Angiotensin II Receptor Antagonist, Thiazide Diuretic
	Type of Form	Form-5
	Finished product Specification	USP

	Pack size & Demanded Price	14's, 28's 2x7;s 4x7's As per PRC
	Approval status of product in Reference Regulatory Authorities.	Micardis HCT (USFDA Approved)
	Me-too status	Registration Number: 073592 Brand Name: Telzimed Manufacturer Name: Mediate
	GMP status	Last inspection report conducted on 24-01-2018 concluding a very good level of GMP compliance.
	Remarks of the Evaluator. AD PEC V	In reference regulatory authorities like in EMA and USFDA the approved drug is multilayered film coated tablet, while the applied drug is single layered uncoated tablet. Approved in USFDA with box warning. Warning: Fetal Toxicity

Decision of 284th meeting of Registration Board:
Deferred for clarification since the applied formulation is approved in reference regulatory authorities as multilayered film coated tablet, while the applied drug is single layered uncoated tablet.

Response by the firm:

Firm has submitted that the approved drug formulation in RRA is multilayered uncoated tablets rather than multilayered film coated tablets. The detail of approved formulation is appended below:

Sr.No	Reference Regulatory Authority	Brand Name	Link
1	USFDA	Micardis HCT	https://www.accessdata.fda.gov/drugsatfda_docs/label/2016 1162s032lbl.pdf
2	EMA	Actelsar HCT	https://www.ema.europa.eu/en/documents/product-information/actelsar-hct-epar-product-information_en.pdf
3	TGA	Micardis Plus	https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/p OpenAgent&id=CP-2010-CMI-02483-3

USFDA label specifies that ***MICARDIS HCT is available in three strengths as biconvex two-layered, oblong-shaped, uncoated tablets containing telmisartan and hydrochlorothiazide***:

Accordingly, the firm has submitted revised formulation along with Form 5 and its annexures as per USFDA along with submission of fee 30,000/- vide slip number 84073693357 dated 26-08-2022. The revised label claim of the firm is as follows:

Each uncoated bilayer tablet contains:
Telmisartan……40mg
Hydrochlorthiazide…..12.5mg

- Firm has also submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022.
- The evidence of availability of bilayered tablet machine is already considered by the Board while considering the other strength of the same product i.e. Balance-H tablets 80/12.5mg in 296th meeting of Registration Board.

Decision: Approved with following label claim:
Each uncoated bilayer tablet contains:
Telmisartan……40mg
Hydrochlorthiazide…..12.5mg

240.	Name and Address of Manufacturer / Applicant	**M/s Wilson's Pharmaceuticals,** 387-388, I-9, Industrial Area, Islamabad.
	Brand Name + Dosage Form + Strength	**Wiltide Plus 50mcg+100mcg Rotacaps**
	Diary No. Date of R & I & fee	Diary No:15455, 18/09/2017, Rs: 20,000/-

	Composition	Each Rotacap contains: Fluticasone propionate …100mcg Salmeterol (as xinafoate) …50mcg
	Pharmacological Group	Adrenergics, Inhalants (Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics)
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	28's, 60's/ As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Seretide Accuhaler 50 microgram /100 microgram /dose inhalation powder, predispensed. by M/s Glaxo Wellcome UK Ltd (MHRA Approved)
	Me-too Status	Not confirmed.
	GMP Status	Last inspection report conducted on 24-01-2018 concluding a very good level of GMP compliance.
	Remarks of the Evaluator.	• Evidence of rotacaps is not found in Reference Regulatory Authorities. This formulation is available as, metered dose dry powder inhaler. • Evidence of rotacaps is not found in available me-too database.
	Decision of 283rd meeting of Registration Board: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Response by the firm: Firm has submitted following documents: • Evidence of Seretide 100 Diskus 50 microgram/100 microgram / dose inhalation powder, pre-dispensed approved in HPRA Ireland. • Me-too status: Seretide Diskus 50/100mcg by GSK • Section approval letter dated 15-09-2021 specifying Dry powder inhaler capsule (Steroidal)-New section. • DPI device: eziHaler (Trademark number 519711) • Delivered dose label claim as: Each delivered dose contains: Salmeterol (as salmeterol xinafoate)……. 47 micrograms Fluticasone propionate……92 micrograms	
	Decision: Approved.	
241.	Name and Address of Manufacturer / Applicant	**M/s Wilson's Pharmaceuticals,** 387-388, I-9, Industrial Area, Islamabad.
	Brand Name + Dosage Form + Strength	**Wiltide Plus 50mcg+250mcg Rotacaps**
	Diary No. Date of R & I & fee	Diary No:15462, 18/09/2017, Rs: 20,000/-
	Composition	Each Rotacap contains: Fluticasone propionate …25mcg Salmeterol (as xinafoate) …50mcg
	Pharmacological Group	Adrenergics, Inhalants (Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics)
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	28's, 60's/ As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Seretide Accuhaler 50 microgram /250 microgram /dose inhalation powder, predispensed. by M/s Glaxo Wellcome UK Ltd (MHRA Approved)
	Me-too Status	Not confirmed.
	GMP Status	Last inspection report conducted on 24-01-2018 concluding a very good level of GMP compliance.
	Remarks of the Evaluator.	• Evidence of rotacaps is not found in Reference Regulatory Authorities. This formulation is available as, metered dose dry powder inhaler.

		• Evidence of rotacaps is not found in available me-too database.
	Decision of 283rd meeting of Registration Board: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Response by the firm: Firm has submitted following documents: • Evidence of Seretide 250 Diskus 50 microgram/250 microgram/dose inhalation powder, pre-dispensed approved in HPRA Ireland. • Me-too status: Seretide Diskus 50/250mcg by GSK • Section approval letter dated 15-09-2021 specifying Dry powder inhaler capsule (Steroidal)-New section. • In the minutes of 283rd meeting of Registration Board, the strength of Fluticasone propionate was inadvertently mentioned as 25mcg instead of 250mcg. • DPI device: eziHaler (Trademark number 519711) • Delivered dose label claim as: Each delivered dose contains: Salmeterol (as salmeterol xinafoate)……. 47 micrograms Fluticasone propionate……231 micrograms	
	Decision: Approved.	
242.	Name and Address of Manufacturer / Applicant	**M/s Wilson's Pharmaceuticals,** 387-388, I-9, Industrial Area, Islamabad.
	Brand Name + Dosage Form + Strength	**Wiltide Plus 50mcg+500mcg Rotacaps**
	Diary No. Date of R & I & fee	Diary No:15456, 18/09/2017, Rs: 20,000/-
	Composition	Each Rotacap contains: Fluticasone propionate …500mcg Salmeterol (as xinafoate) …50mcg
	Pharmacological Group	Adrenergics, Inhalants (Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics)
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	28's, 60's/ As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Seretide Accuhaler 50 microgram /500 microgram /dose inhalation powder, predispensed. by M/s Glaxo Wellcome UK Ltd (MHRA Approved)
	Me-too Status	Not confirmed.
	GMP Status	Last inspection report conducted on 24-01-2018 concluding a very good level of GMP compliance.
	Remarks of the Evaluator.	• Evidence of rotacaps is not found in Reference Regulatory Authorities. This formulation is available as, metered dose dry powder inhaler. • Evidence of rotacaps is not found in available me-too database.
	Decision of 283rd meeting of Registration Board: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Response by the firm: Firm has submitted following documents: • Evidence of Seretide 500 Diskus 50 microgram/500 microgram/dose inhalation powder, pre-dispensed approved in HPRA Ireland. • Me-too status: Seretide Diskus 50/500mcg by GSK • Section approval letter dated 15-09-2021 specifying Dry powder inhaler capsule (Steroidal)-New section. • DPI device: eziHaler (Trademark number 519711)	

	• Delivered dose label claim as: Each delivered dose contains: Salmeterol (as salmeterol xinafoate)……. 47 micrograms Fluticasone propionate……460 micrograms
	Decision: Approved.

Veterinary deferred cases

243.	**Name and address of manufacturer / Applicant**	**M/s Intervac (Pvt) Ltd., 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan**
	Brand Name +Dosage Form + Strength	Oxytofas- DS Injection
	Composition	Each 100ml contains: Oxytocin (Synthetic)…….2000IU
	Diary No. Date of R& I & fee	Dy.No.8144; 10-07-2017; Rs.20,000/- (10-07-2017)
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	100ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Oxytovet Injection Of M/S International Pharma Labs.
	GMP status	Last inspection conducted on 28-02-2017 & 17-03-2017 and report concludes that panel recommend the renewal of injectable section (veterinary) and vaccines section (veterinary).
	Remarks of the Evaluator	
	Decision of 288th meeting of Registration Board: Deferred for the clarification of manufacturing outline as its not inline with the product approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
	Response by the firm: Firm has submitted me-too status along with print out from DRAP website database of registered drugs as follows Name: Oxytovet Injection Manufacturer: International Pharma Registration Number: 074756	
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	

Agenda of Evaluator PEC-I:

Case No. I: Registration applications submitted on Form 5F (Local Manufacturing)
New Cases:

244.	Name, address of Applicant / Marketing Authorization Holder	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area Islamabad.
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1025 dated 05-10-2021
	Details of fee submitted	PKR 30,000/-: dated 03-06-2021
	The proposed proprietary name / brand name	Sunny D PFS 5mg/mL Pre-Filled Syringe
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each PFS (1mL) contains: Cholecalciferole……..5mg
	Pharmaceutical form of applied drug	Clear and sterile Solution for IM injection in Pre-Filled Syringe
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1's, 3's, 5's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	1. Vitamin D3 Bon 200000 IU /1mL Solution for injection, ANSM France Approved.
	For generic drugs (me-too status)	Indrop D Injection M/s Neutro Pharmaceutical Pvt Ltd Pakistan., Reg. No. 023170
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. F.3-14/2018-Addl.Dir.(QA&LT-I) (for Government supply/Institution only) issued on the basis of inspection conducted on 09/11/2020. The firm has stated the applied product is being manufactured in General ampoule section.
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited Z-109 B&C, SEZ II, Dahej Taluka, Vagara Dist: Bharuch 392130 Gujarat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25°C ± 2°C / 60% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months B: CLC0416005, CLC0416006, CLC0416007
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence is established against Indrop D Batch : HP813 by performing all the quality tests.
	Analytical method validation/verification of product	Method validation studies are submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Fermenta Biotech Limited Z-109 B&C, SEZ II, Dahej Taluka, Vagara Dist: Bharuch 392130 Gujarat India.		
API Lot No.	CLC0419050		
Description of Pack (Container closure system)	Type I transparent and glass tube with luer lock system (rigid cap).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	500 PFS	500 PFS	500 PFS
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	30/08/2020	30/08/2020	30/08/2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted that in 278th meeting, the panel constituted for verification of authenticity of stability data submitted the report and the board approved the case of Dascot 30mg & 60mg (Daclatasvir) tablets.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2062043 valid till 17/06/2023 is submitted issued by Food & Drugs Control Administration Gujarat India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of attested invoice Dy. No. 2166 dated 19/07/2019 is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator-I:		

Sr. No.	Observations	Response
1	Provide analytical method validation/verifications studies including specificity, precision and accuracy for Drug substance along with the method of analysis used for routine analysis of drug substance.	The firm has submitted verification studies for drug substance and submitted detail of analytical method.
2	Since the excipients used in the formulation are different from the innovator's product therefore, compatibility studies of excipients with drug substance is required.	Drug-Excipient compatibility studies are not submitted.
3	The product approved in reference country is Ampoule while the applied product is PFS. Keeping in view, please provide justification or otherwise provide any reference product in PFS dosage form.	The firm has stated that Pahramceutical Equivalence is established against Indrop-D whereas the dosage form, strength and route of administration are same.
4	Please provide GMP certificate / drug manufacturing license of drug substance manufacturer.	Copy of GMP certificate No. 2062043 valid till 17/06/2023 is submitted issued by Food & Drugs Control Administration Gujarat India.
5	Provide analytical method validation / verifications studies performed by drug product manufacturer for analysis of drug substance including specificity, linearity and precision.	Analytical method verification studies are submitted.
6	Submit the documents (Invoice etc) confirming the procurement of drug substance with approval from DRAP since you have submitted the required documents (invoice, airway bill, form 5 etc) of M/s DSM Nutritional products France while the manufacturer of drug substance is M/s Fermenta Biotech Limited Z-109 B&C, SEZ II, Dahej Taluka, Vagara Dist: Bharuch 392130 Gujarat India.	*"We are importing the vitamin D3 from DSM and as well as Fermenta for manufacturing of our registered products Sunny D Absorba and Sunny d Insta Ampoule containing vitamin D3. We had mistakenly submitted the DSM invoices instead of Fermenta one. Now we are submitting the Fermenta documents".* Copy of attested invoice Dy. No. 2166 dated 19/07/2019 is submitted.
7	Submit COA of drug substance from drug product manufacturer as well as from the drug substance manufatcurer along with the calculations for potency adjustment considering the assay value.	The firm has submitted COAs from drug substance manufacturer and drug product manufacturer for Lot no. CLC0419050 along with the calculations for potency adjustment.

Decision: The Board discussed that the container closure for the applied product is Pre-Filled Syringe (PFS) which is different from the innovator's product which is Glass ampoule. Since container closure for the applied product as well as the innovator's product is Type I glass Ampoule and the product development / stability studies of the applied product demonstrated that there is no incompatibility between the material of container and the formulation, therefore, the Board decide to approve the case.

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

245.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilshire Laboratories (pvt) Ltd., 124/1 Quaid e Azam Industial Estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Wilshire Laboratories (pvt) Ltd., 124/1 Quaid e Azam Industial Estate, Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31770 dated 18/11/2021
	Details of fee submitted	PKR 30,000/-: dated 20/05/2021
	The proposed proprietary name / brand name	Zoleda 4mg/5mL Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial (5mL) contains: Zoledronic acid as monohydrate……4mg
	Pharmaceutical form of applied drug	Clear, lightly yellow Liquid Injectable solution
	Pharmacotherapeutic Group of (API)	Anti-Hypercalcemic agent used n Malignancy
	Reference to Finished product specifications	In-House
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zometa 4mg/5mL injection, USFDA Approved.
	For generic drugs (me-too status)	ZOLEDRONIC ACID INJECTION 4MG/5ML by M/s ZAYNEB SCIENTIFIC PRODUCTS, Reg. No. 72523
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 144/2022-DRAP(AD-4119611790) issued on the basis of inspection conducted on 14/09/2022.
	Section approval	Liquid Injection (General) section
	Name and address of API manufacturer.	M/s Shandong New Time Pharmaceutical Co., Ltd., No. 1 north outer ring road, Feixian, Shandong china.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Zoledronic acid is non-pharmacopoeial drug susbance.Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities (A &B), residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards (Empagliflozin RS and impurities), container closure system and stability studies of drug substance.

	Stability studies	• Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months • Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (502170801, 502170901, 502170902)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Phamaceutical equivalence testing is performed against Zometa 4mg/5mL Injection by M/s Novartis by performing quality tests.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy/recovery, precision, specificity, LOD/LOQ, Robustness, Solution stability, system suitability

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong New Time Pharmaceutical Co., Ltd., No. 1 north outer ring road, Feixian, Shandong china.		
API Lot No.	502190795		
Description of Pack (Container closure system)	1x5ml Glass Vial packed in bleach board Unit carton with leaflet. COAs & Analytical methods of Packaging Materials are Enclosed.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1000	1000	1000
Manufacturing Date	09/20	09/20	09/20
Date of Initiation	04-09-2020	04-09-2020	04-09-2020
No. of Batches	03		

Administrative Portion

2.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm.
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD2015021 valid till 12/07/2020.
4.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice No. HH-92-01-07 dated 27/02/2020 dy. No. 3455/2020-DRAP dated 05/03/2020.
5.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
7.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Observations	**Response**
Provide latest GMP inspection report / GMP certificate not older than 3 years.	Copy of GMP certificate No. 144/2022-DRAP(AD-4119611790) issued on the basis of inspection conducted on 14/09/2022.
Analytical method verification studies for drug substance performed by drug product manufacturer including specificity, accuracy and precision.	The firm has submitted Analytical method verification studies for drug substance performed by drug product manufacturer.
The submitted COA of the drug substance from drug product manufacturer concludes that the sample complies with BP specifications while the DS is not present in any pharmacopoeia, please clarify.	Drug substance complies with In-House specification & B.P. Mentioned on COA is due to Typographical Mistake.
As per COA of drug substance from the manufacturer, the product complies with USP pending monograph. Pending monograph is not usually final according to which the product is developed, please provide scientific rationale for selecting pending monograph instead of developing in-house specifications.	The firm has stated that the specification were developed keeping in view the pending USP monograph of USP and the product is developed according to In-House specifications.
Provide batch number, manufacturing date and expiry date of Zometa 4mg/5mL injection against which the pharmaceutical equivalence is established.	Pharmaceutical equivalence testing is performed against Zometa 4mg/5mL Injection by M/s Novartis USFDA approved by performing quality tests.
Please provide justification of specifications for drug product.	The firm has submitted the justification of specifications.
Details of section 3.2.P.6 and 3.2.P.7 are not provided in the submitted dossier, please submit relevant details under relevant sections.	Submitted.
Analytical method validation studies for drug product are not provided in the submitted dossier, please submit relevant data.	The firm has submitted analytical method validation studies including system suitability, precision, accuracy, robustness linearity, filter compatibility, specificity etc for drug product.
Provide complete batch manufacturing record for the applied product.	Submitted.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.

Decision: Approved with innovator's specifications.

- **Registration Board further decided that registration letter will be issued after submission of applicable fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

246.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilshire Laboratories (pvt) Ltd., 124/1 Quaid e Azam Industial Estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Wilshire Laboratories (pvt) Ltd., 124/1 Quaid e Azam Industial Estate, Kot Lakhpat Lahore.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31771 dated 18/11/2021
	Details of fee submitted	PKR 30,000/-: dated 20/05/2021
	The proposed proprietary name / brand name	Zoleda 5mg/100mL injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100mL vial contains: Zoledronic aid as monohydrate…..5mg
	Pharmaceutical form of applied drug	Clear, lghtly yellow Liquid Injectable solution
	Pharmacotherapeutic Group of (API)	Anti-Hypercalcemic agent used n Malignancy
	Reference to Finished product specifications	In-House
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Reclast 5mg/100mL injection, USFDA Approved.
	For generic drugs (me-too status)	Macdronic infusion 5mg/100mL by M/s Macter, Reg. No. 80656
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 268//2019-DRAP(AD-823336-703_ issued on the basis of inspection conducted on 08/08/2019.
	Section approval	Liquid Injection (General) section
	Name and address of API manufacturer.	M/s Shandong New Time Pharmaceutical Co., Ltd., No. 1 north outer ring road, Feixian, Shandong china.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Zoledronic acid is non-pharmacopoeial drug susbance.Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities (A &B), residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards (Empagliflozin RS and impurities), container closure system and stability studies of drug substance.

	Stability studies	• Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months • Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (502170801, 502170901, 502170902)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence testing is performed against Aclasta 5mg/100mL Injection by M/s Novartis by performing quality tests.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy/recovery, precision, specificity, LOD/LOQ, Robustness, Solution stability, system suitability

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong New Time Pharmaceutical Co., Ltd., No. 1 north outer ring road, Feixian, Shandong china.		
API Lot No.	502190795		
Description of Pack (Container closure system)	1x100ml Glass Vial packed in bleach board Unit carton with leaflet. COAs & Analytical methods of Packaging Materials are Enclosed.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1000	1000	1000
Manufacturing Date	09/20	09/20	09/20
Date of Initiation	06-09-2020	06-09-2020	06-09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD2015021 valid till 12/07/2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice No. HH-92-01-07 dated 27/02/2020 dy. No. 3455/2020-DRAP dated 05/03/2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Observations	**Response**
Provide latest GMP inspection report / GMP certificate of drug product manufacturer not older than 3 years.	Copy of GMP certificate No. 144/2022-DRAP(AD-4119611790) issued on the basis of inspection conducted on 14/09/2022.
Analytical method verification studies for drug substance performed by drug product manufacturer including specificity, accuracy and precision.	The firm has submitted Analytical method verification studies for drug substance performed by drug product manufacturer.
The submitted COA of the drug substance from drug product manufacturer concludes that the sample complies with BP specifications while the DS is not present in any pharmacopoeia, please clarify.	Drug substance complies with In-House specification & B.P. Mentioned on COA is due to Typographical Mistake.
As per COA of drug substance from the manufacturer, the product complies with USP pending monograph. Pending monograph is not usually final according to which the product is developed, please provide scientific rationale for selecting pending monograph instead of developing in-house specifications.	The firm has stated that the specification were developed keeping in view the pending USP monograph of USP and the product is developed according to In-House specifications.
Provide batch number, manufacturing date and expiry date of Aclasta 5mg/100mL injection against which the pharmaceutical equivalence is established along with the details of approval status of the product in reference countries.	Pharmaceutical equivalence testing is performed against Aclasta 5mg/100mL Injection by M/s Novartis, UK approved by performing quality tests.
Please provide justification of specifications for drug product.	The firm has submitted the justification of specifications.
Details of section 3.2.P.6 and 3.2.P.7 are not provided in the submitted dossier, please submit relevant details under relevant sections.	Submitted.
Analytical method validation studies for drug product are not provided in the submitted dossier, please submit relevant data.	The firm has submitted analytical method validation studies including system suitability, precision, accuracy, robustness linearity, filter compatibility, specificity etc for drug product.
Provide complete batch manufacturing record for the applied product.	Submitted.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.

Decision: Approved with innovator's specifications.

- **Registration Board further decided that registration letter will be issued after submission of applicable fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

247.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited B-23-C, SITE Karachi.
	Name, address of Manufacturing site.	M/s AGP Limited B-23-C, SITE Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33118 dated 07/12/2021
	Details of fee submitted	PKR 30,000/-: dated 13/07/2021
	The proposed proprietary name / brand name	Femizo tablet 2.5mg Alternate brand names: Lozimol Ozirol Lites
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet: Letrozole……2.5mg
	Pharmaceutical form of applied drug	Film coated immediate release tablet
	Pharmacotherapeutic Group of (API)	Aromatase inhibitor
	Reference to Finished product specifications	USP
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Femara 2.5mg tablet, USFDA Approved.
	For generic drugs (me-too status)	Femara 2.5mg by M/s Novartis Pharma
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 30/2021-DRAP(K)issued on the basis of inspection conducted on 03/06/2021.
	Name and address of API manufacturer.	M/s Jiangsu Nhwa Sede Phamaceutical Co., Ltd., No.3 Fumin road the third industrial park, hi-the industrial development zone, Xuzhou, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions:

		• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months for 3 batches Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months of 02 batches Batches: 20150101, 20150201, 20150202
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence is established against the innovator's product that is Femara 2.5mg Batch Number by performing quality tests. CDP is performed against the innovator's product Femara (B:TFH38) using 0.1N HCL, acetate buffer and phosphate buffer as dissolution media.
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangsu Nhwa Sede Phamaceutical Co., Ltd., No.3 Fumin road the third industrial park, hi-the industrial development zone, Xuzhou, China.		
API Lot No.	20191224		
Description of Pack (Container closure system)	Alu-PVC blister of 3×10's packed in a secondary unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	Tr-604	Tr-605	Tr-606
Batch Size	2500tablet	2500tablet	2500tablet
Manufacturing Date	April-2020	April-2020	April-2020
Date of Initiation	07/05/2020	07/05/2020	07/05/2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has provided following reference; Glyzia-XR Tablet 50/50mg approved in 285th meeting after submission of panel inspection report.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy g GMP certificate No. JS20160578 valid till 24/07/2023. Copy of DML No. SU20160110 valid till 17/12/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted ADT attested invoice No. FW/1N 20N-001 dated 26/02/2020 dy. No. 0654.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of digital data logger.

Remarks OF Evaluator-I:

Observations	Response
Provide stability studies of the drug substance as per the conditions of zone IV-A since the submitted data is not according to zone IV-A or otherwise provide degradation studies on drug product as per the decision of Registration Board.	Stability study conditions: • Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months for 3 batches Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months of 02 batches Batches: 20150101, 20150201, 20150202
Please provide batch number, expiry date and date of manufacturing of the innovator's product against which pharmaceutical studies have been performed.	Pharmaceutical equivalence is established against the innovator's product that is Femara 2.5mg Batch Number (B: TFH38 & SRN50) by performing quality tests. CDP is performed against the innovator's product Femara (B:TFH38) using 0.1N HCL, acetate buffer and phosphate buffer as dissolution media.
Provide verifications studies for analytical method for drug substance performed by drug product manufacturer.	*"We have conducted analytical testing as per USP specifications and procedures. An undertaking is enclosed submitted that we will perform the verification studies of analytical method for the drug substance before the launch of the product"*
The test for inter-day precision has not been performed for analytical method verifications studies for drug product, please provide the required result.	The firm has not performed test for Inter-day precision.
Submit Batch Manufacturing records for all the three batches along with the detail of calculations for potency adjustment considering the COA (from drug product manufacturer) of the relevant batch used for product development.	The firm has submitted complete BMR for the applied product.

Decision: Approved with innovator's specifications.

- **Registration Board further decided that registration letter will be issued after submission of applicable fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will provide analytical method verification studies for dug substance as per USP including specificity, accuracy and precision before the issuance of registration letter.**

Case No. II: Registration applications submitted on Form 5F (Import)
New Cases:

248.	Name, address of Applicant / Importer	M/s AJM Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Pakistan.
	Details of Drug Sale License of importer	**License No: 064**

		Address: AJM Pharma Pvt. Ltd., 1st Floor, Shafi Court, Civil Lines, Merewether Road, Karachi, Pakistan. **Address of Godown:** • Ground floor plot no. 44, sector 27 KIA Karachi. • Shed No. F-9 Plot No. S1, survey No. 230 sector-02 road 4000 korangi industrial area,Karachi **Validity:** 23/02/2023 **Status:** by way of whole sale
	Name and address of marketing authorization holder (abroad)	M/s Qilu Pharmaceutical Co., Ltd., No.8888 Lvyou rod, High-tech zone, Jinan 250104, Shandong province, China.
	Name, address of manufacturer(s)	M/s Qilu Pharmaceutical Co., Ltd., No.8888 Lvyou rod, High-tech zone, Jinan 250104, Shandong province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate) • Original, legalized and valid copp (no. Shandong20210223(I) valid till 08/07/2023 issued by the first branch of regional inspection of Shandong Drug Administration. The applied product is present in the market f exporting country for free sale. The facilities and operations conform to Chinese GMP. • Copy of GMP certificate No. SD20170581 valid till 05/07/2022. The scope of inspection includes Tablets (Anti-neoplastic). • Copy of GMP certificate No.ES/098HV/21 issued by CIMA Spain issued on the basis of inspection conducted on 25/03/2021.	
	Details of letter of authorization / sole agency agreement • Letter of authorization from M/s Qilu Pharmaceutical Co., Ltd., is submitted. M/s AJM Pharma Pvt. Ltd., is authorized for import and distribution of the applied product.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.
	Details of fee submitted	PKR 100,000/-: 13-08-2018
	The proposed proprietary name / brand name	Abiraterone Acetate Tablet 250mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Abiraterone acetate……..250mg
	Pharmaceutical form of applied drug	Immediate release tablet
	Pharmacotherapeutic Group of (API)	Drugs for endocrine therapy
	Reference to Finished product specifications	USP
	Proposed Pack size	120tablets per bottle
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Zytiga (250mg & 500mg) tablet, USFDA Approved.
	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Name, address of drug substance manufacturer	M/s Shandong Anhong Pharmaceutical Co., Ltd., No. 29 Huayuan street Linyi County. Dezhou, Shandong 251500 China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months of 3 batches Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months of 3 batches Batches: (7001BL71B, 7002BL71B, 7003CL71B)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative dissolution profile is submitted against the reference product Zytiga 250mg tablet, USFDA (B:HAZSK00) approved in all the 03 media that is 0.1N HCl, Phosphate buffer (4.5pH and 6.8pH). F2 values are in the limit.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle (150cc) with 38mm child resistant cap (CRC) containing 120 tablets.
	Stability study data of drug product, shelf life and storage conditions	Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months of 3 batches Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months of 3 batches Batches: (17F0053DD9, 17H0073DD9, 17H0093DD9)

Evaluation by PEC-I:
Indications:
It is a CYP17 inhibitor indicated in combination with prednisone for the treatment of patients with

• metastatic castration-resistant prostate cancer (CRPC).
• metastatic high-risk castration-sensitive prostate cancer (CSPC)

Sr. no.	Observations	Response
1	For Abiraterone drug substance, the assay is calculated by the drug substance manufacturer by taking the assay value of Abiraterone (DS) on Anhydrous basis while the drug product manufacturer has used the assay value on As-Is basis, please provide scientific rational for the difference in the analytical methods used.	*"The assay test of pharmaceutical used substance is being performed without rendering to anhydrous state. The result of assay is termed as assay on as-is basis. The water present in a pharmaceutical used substance is not considered as an impurity and hence the result of water content test in accounted in the result of assay on as-is basis. The water content is accounted in assay on as-is basis mathematically by using industry-accepted formula for assay on anhydrous basis. The industry-accepted formula is written as (assay on as-is basisxl00)/(100-%water) and outcome of formula is termed as assay on anhydrous basis".*
3	Provide pharmaceutical equivalence studies performed against reference product along with the batch number, expiry and manufacturing date of the reference product.	Pharmaceutical equivalence conducted against reference listed drug ZYTIGA having following details, Testing Results for RLD and Generic Drug Product is also attached Lot#: YGWS Exp.: May, 2019 Mfg Date :April, 2017
4	In CDP, Phosphate Buffer with 4.5 pH and 6.8 pH is used as dissolution media. Usually for dissolution media of lower pH, Acetate Buffer is used. Please provide scientific justification for not using Acetate Buffer (4.5) and selecting Phosphate Buffer of 4.5pH. Provide reference of relevant guidelines if any.	*"For phosphate buffer 4.5 over acetate buffer: that is because the QC release medium is 0.25% SLS in 56.5 mM phosphate buffer, pH 4.5. So for pH 4.5 buffer, we also use the phosphate buffer"* The firm has provided following weblink frpm USFDA Dissolution data base where Phosphate Buffer with 4.5pH has been used for dissolutn testing. *https://www.accessdata.fda.gov/ scripts/cder/dissolution/dsp_SearchResults.cfm*
5	The acceptance criteria for accuracy parameter of analytical method validation studies for drug product is 95%-105%. Please provide the reference.	*"For acceptance limit selected for validation study: According to USP <1092> The dissolution procedure: development and validation Item 5.3 Accuracy/Recovery, "The measured recovery is typically 95%-105% of the amount added."*
6	Provide real time stability studies conducted under the conditions of Zone IV-A for 03 batches till claimed shelf life of 2 years.	*"In support of our proposed expiration date, stability data was generated for up to 24 months storage under long term conditions (30 ± 2°C/65±5% RH), and 6 months storage under accelerated conditions (40 ± 2°C/75 ± 5% RH). Documents for your reference attached in which the results of stability testing performed on following batches are summarized"* Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months of 3 batches Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months of 3 batches Batches: (17F0053DD9, 17H0073DD9, 17H0093DD9)

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

249.	Name, address of Applicant / Importer	M/s Genetech Laboratroies, 246-B, Block 6, PECHS Karachi.

	Details of Drug Sale License of importer	License No: 0002 Address: Genetech Laboratroies, 246-B, Block 6, PECHS Karachi. Address of Godown: N/A Validity: 15/08/2022 Status: by the way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Daru Pajuthan Pardis No. 4&8, north Tak St., Attar St., Vanak Sq., Tehran , Iran.
	Name, address of manufacturer(s)	M/s Sobhan Oncology Pharmaceutical co., Ltd., No. 357, 3'd st., Sanat 2 Blvd., Rasht Industrial City, Rasht- Iran.
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Firm has submitted original, legalized COPP certificate (No. 665/101696) dated 20/01/2021 issued by Fodd and Drug Adminsitration, Iran. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. • Embassy attested translated copy of free sales certificate (No. 129800) is attached. Authorization for Distribution and sale at selected pharmacy is granted. • Copy of GMP certificate No. 665/58453 dated 10/09/2020 on the basis of inspection conducted on August, 2020. Validity: 1 year Activity: Manufacturing of cytotoic product Manufacturing operations include	
	Details of letter of authorization / sole agency agreement: • The applicant has submitted NOC from the product license holder to register, import and market the applied product that is Palbocap in the favour of M/s Gene Tech Laboratories Pakistan. • Copy of contract agreement between the applicant and product license holder (abroad) is also submitted.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 1082 dated 02-12-2021
	Details of fee submitted	PKR 100,000/-: dated 24-03-2021 PKR 50,000/- dated 28/06/2021.
	The proposed proprietary name / brand name	Palcocap 125mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Palbociclib…….125mg
	Pharmaceutical form of applied drug	Immediate release capsule
	Pharmacotherapeutic Group of (API)	Anti-neoplastic / Protein kinase Inhibitor
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	Pack of 21 capsule

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ibrance Capsule (75mg, 100mg, 125mg), USFDA Approved.
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and product.
	Name, address of drug substance manufacturer	M/s Acebright (India) Pharma Private Limited, No. 77D & 116/1117, KIADB Industrial Area, Jigani, Banglore – 560 105 Karnataka India.
	Module-III Drug Substance:	The drug substance belongs to BCS class II drugs. Crystalline anhydrous form A is the most thermodynamically stable form used in the manufacturing. Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• Real time stability studies have been conducted at 25°C±2 and 60%RH±5% for 12 months of 3 batches • Accelerated stability study is conducted at 40°C±2 and 75%RH±5% for 6 months of 3 batches Batches: PBCA18003, PBCA18004, PBCA18005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative dissolution profile is submitted against Ibrance 125mg Capsule, USFDA Approved. F2 and F1 values are within the limits (Batch Number; EF1902). Pharmaceutical quivalenc is established agains the reference product (Ibrance 125mg Capsule).
	Analytical method validation/verification of product	Analytical validations studies for drug substance as well as for drug product are submitted.
	Container closure system of the drug product	White HDPE bottle containing 21 capsule and a paper filter bad of Silca Gel.

	Stability study data of drug product, shelf life and storage conditions	• Real time stability studies have been conducted at 30oC±2 and 65%RH±5% for 18 months of 03 batches • Accelerated stability studies is conducted at 40oC±2 and 75%RH±5% for 6 months of 03 batches B: 0006, 0007, 0008

Evaluation by PEC-I:
The firm has submitted real time stability data of 18 months for drug product.

Sr. No.	Observations	Response
1	Please provide analytical method verification studies including specificity, accuracy and precision performed by drug product manufacturer.	The firm has submitted analytical method validation studies for drug substance from finished product manufacturer including specificity, precision and accuracy.
2	Justify the dissolution specification with special reference to Q value which should be achieved in 30 minutes (sampling time) as per available literature of the innovator's product but for the applied product the more than 85% of drug should be released in 45 minutes.	*The dissolution method is selected based on FDA Dissolution Method. Although the release profile of Palbocap is equal to IBRANCE, which, both of them have been released over 85% in 15 minutes.*
3	Please provide pharmaceutical equivalence studies against the innovator's / reference product by performing all the quality tests.	The firm has submitted bioequivalence data against Ibrance 125mg Capsule.
4	Since the concentration range of 0.025mg/mL to 0.15mg/mL is selected for testing the Accuracy and linearity parameters of analytical method validations studies for drug product while 0.5mg/mL solution is prepared for analysis, please justify the amount used for preparation of sample solution.	*The concentration of prepared solution for assay analysis is 0.125 mg/mL (500 mg of weighted powder is equivalent to 125 mg palbociclib), we prepare 25% - to 150% (0.0312-0.187 mg/mL) of this concentration for accuracy and linearity analysis.*
5	Please justify the limit of moisture content which in NMT 5% for drug product whereas the specification for drug substance include loss on drying with a limit of NMT 1%.	*This percentage justified because of production limitation and we have stability data of product in this situation*

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

- **Registration Board decided that the applicant shall revise the dissolution specifications from "NLT 85% in 45 minutes" to "NLT 85% in 30 minutes" as per the reference product.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.**

Case No. III: Registration applications submitted on Form 5 (Local manufacturing)
Deferred Cases:

250.	Name and address of manufacturer / Applicant	"M/s Medicon Pharmaceuticals Pvt Ltd. Industrial Estate, Jamrud Road, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Medisartan 5/80 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate……5mg Valsartan……..80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38248 dated 20-11-2018 Rs.20,000/- Dated 20-11-2018 (Slip# 0749867)
	Pharmacological Group	Calcium channel blocker/Angiotensin-II receptor antagonists
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1x14's As per SRO

	Approval status of product in Reference Regulatory Authorities	Exforge Approved by MHRA of UK
	Me-too status	Exforge Tablet of M/s Novartis Pharma (Reg.#047569)
	GMP status	Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of the Evaluator	
	Previous decision (M293)	Deferred for clarification of Salt form API.
	Submission by the firm: The firm has submitted: • The firm has revised the formulating from "Amlodipine Besylate 5mg to Amlodipine As Besylate 5mg" as per the reference product and submitted Rs. 7,500/- vide challan number 84040225 dated 29/08/2022. Each Film Coated Tablet Contains: Amlodipine as Besylate…..5mg Valsartan……..…80mg • Copy of last GMP inspection report dated 14/12/2020, Satisfactory level of GMP compliance.	
	Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of remaining fee for pre-registration variation that is Rs. 22,500/- for revision of formulation and revision of specifications as per the innovator's product as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
251.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Hb-Ron Syrup 60 ml, 120 ml
	Composition	Each 5 ml contain: Iron (III) hydroxide polymaltose complex eq. to elemental iron…….50mg Folic acid…….0.35mg
	Diary No. Date of R& I & fee	Dy No. 1683: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Iron in combination with folic acid
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	60mL, 120mL, as per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	054851; Bioron F Syrup 120ml M/s Shaheen Pharmaceuticals,Swat
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no.S-66, 5200 Bottles was "Ordered not to dispose off" due to poor anitation & hygiene conditions in the oral liquid filling area.
	Remarks of the Evaluator	
	Previous decision (M287)	Deferred for the following: i) Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. ii) Submission of fee for revision of formulation.
	Submission by the firm: • Copy of last GMP inspection report dated 14/12/2020, Satisfactory level of GMP compliance. • The firm has submitted Rs. 7,500/- vide challan number 965174160117 dated 11/02/2022 for revision of formulation from Folic Acid 0.5mg to 0.35mg. Each 5 ml contain: Iron (III) hydroxide polymaltose complex eq. to elemental iron…….50mg Folic acid…….0.35mg	

	Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of remaining fee for pre-registration variation that is Rs. 22,500/- for revision of formulation and revision of specifications as per the innovator's product as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
252.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Metasone GM/Metacort Plus Cream
	Composition	Each gram cream contains: Betamethasone (as valerate)……1.2mg Gentamycin (as sulfate)…….1mg Miconazole (as nitrate)……20mg
	Diary No. Date of R& I & fee	Dy No. 1686: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics and antifungal
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	20g; As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no.S-66, 5200 Bottles was "Ordered not to dispose off" due to poor anitation & hygiene conditions in the oral liquid filling area.
	Remarks of the Evaluator	□ The firm was asked to submit complete finished product specifications and testing methods. However, the firm submitted specifications without complete testing method. □ The brand name shall be changed
	Previous decision (M287)	Decision: Deferred for the following: □ Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. □ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. □ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Submission by the firm: • Copy of last GMP inspection report dated 14/12/2020, Satisfactory level of GMP compliance. The firm has revised the formulation from Betamethasone as Valerate 1.2mg/g to Betamethosone as valerate 1mg/g and submitted rs. 7,500/- vide challan number 26027666328 dated 11/02/2022. Each gram cream contains: Betamethasone (as valerate)……1.2mg Gentamycin (as sulfate)…….1mg Miconazole (as nitrate)……20mg • Generic status: Mycona-GB cream by M/s Valor Pharmaceuticals, Reg. No. 066358 • RRA Status: could not be confirmed **Decision: Deferred for:** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

253.	Name and address of manufacturer / Applicant	M/s Vega Pharmaceuticals (PVT) LTD. Plot No.4, Pharma city Sunder 30KM Multan road Lahore.
	Brand Name +Dosage Form + Strength	MOMAT Nasal spray (50mcg/spray)
	Diary No. Date of R& I & fee	Dy.No. 33945 dated 12/10/2018 PKR 20,000/-
	Composition	Each spray contains: Mometasone furoate…… 50mcg
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	Price Rs.300/- per bottle of 20ml
	Approval Status of Product in Reference Regulatory Authorities	APO-MOMETASONE aqueous nasal spray by M/s Apotex Inc. Health Canada approved
	Me-too Status	Memocart nasal spray by M/s Platinum Pharma Karachi, Reg no. 36585
	GMP Status	Last inspection report dated 17/07/2017 concluded that the firm has maintained good level of GMP compliance. The firm has Eye Drops (Steroidal) Section.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for confirmation of required manufacturing facility / section Nasal Spray from Licensing Division. Submission by the firm: • The firm has been granted change of title from "Eye Drops (Steroid) section" to Eye/Ear Drops & Nasal Spray (Steroid) Section" vide letter No. F.1-22/2001-Lic(Vol-II) dated 19/05/2022.	
	Decision: Approved. The Board further decided that the registration letter will be issued after submission of latest inspection report valid within the last three years.	

254.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 1gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16256 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 1000mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82749
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. Registration Board decided that the registration letter will be issued after submission of latest inspection report valid within the last three years for M/s Jinnah Pharmaceutical Pvt. Ltd and M/s Aventek Pharmaceuticals. • **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	

255.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 500mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16255 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…500gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 500mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82750
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
256.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Pime 1gm IV Injection
	Diary No. Date of R& I & fee	Dy.No 16566 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Cefepime as HCl…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride 1gm with L-Arginine Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 1gm Injection by M/s Bosch, Reg. No. 44357
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	

	Decision: Approved as per following label claim: **"Each vial Contains:** **Cefepime as hydrochloride (with L-Arginine) ……1gm"** • **Registration letter will be issued upon submission of full fee that is 75,000/- for pre-approval change/correction in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
257.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Pime 500mg IV Injection
	Diary No. Date of R& I & fee	Dy.No 16565 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Cefepime as HCl…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride with L-Arginine 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 500mg Injection by M/s Bosch, Reg. No. 44356
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved as per following label claim: **"Each vial Contains:** **Cefepime as hydrochloride (with L-Arginine) ……500mg"** • **Registration letter will be issued upon submission of full fee that is 75,000/- for pre-approval change/correction in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
258.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 250mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16247 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone (250mg & 1gm) powder for solution for injection by M/s Villerton Invest SA, MHRA Approved.
	Me-too Status	Unixone Injection 250mg IM by M/s Caliph pharmaceuticals (Pvt.) Ltd, Reg. no. 82556
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
259.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 250mg IM Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16254 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…250gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	CEFTAZIDIME PANPHARMA CHILDREN AND INFANTS 250 mg powder for solution for injection by M/s PANPHARMA MHRA Approved.
	Me-too Status	Fortez Injection 250mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
260.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 500mg IM Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16250 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg

	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark pharmaceutical, Reg. No. 69751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
261.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 500mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16249 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark pharmaceutical, Reg. No. 69751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
262.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 1g IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16251 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains:

		Ceftriaxone as Sodium…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 1000mg Injection by M/s WelMark Pharmaceutical, Reg. No. 69752
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
263.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 100mg/5ml Dry Powder Suspension
	Diary No. Date of R& I & fee	Dy.No 16257 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each 5ml (reconstituted) Contains: Cefixime as Trihydrate…100mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30ml bottle, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
264.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 200mg/5ml Dry Powder Suspension
	Diary No. Date of R& I & fee	Dy.No 16258 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019

	Composition	Each 5ml (reconstituted) Contains: Cefixime as Trihydrate…200mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30 ml bottle, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Xerak Oral Dry Powder Suspension (200mg/5ml) by M/s CKD, Reg. No. 81788
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
265.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 400mg Capsule
	Diary No. Date of R& I & fee	Dy.No 16259 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Capsule Contains: Cefixime as Trihydrate….400mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Suprax (cefixime as trihydrate) 400mg capsule by M/s Lupin ltd, USFDA approved.
	Me-too Status	Xalfocin 400mg Capsule by M/s Martin Dow (Reg. # 080646)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
266.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 1gm IV Dry Powder Injection

	Diary No. Date of R& I & fee	Dy.No 16252 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…500mg Cefoperazone as Sodium…500mg
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
267.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 2gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16253 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…1gm Cefoperazone as Sodium…1gm
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Approved by 3 European countries: **Czech:** http://www.sukl.eu/modules/medication/detail.php?code=0015 273&tab=info **Slovakia:** https://www.sukl.sk/hlavna-stranka/english-version/specialpages/medical-product-detail?page_id=842&lie_id=6343A **Poland:** http://pub.rejestrymedyczne.csioz.gov.pl/?AspxAutoDetectCookieSupport=1#results
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained

		satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	
268.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 2gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16252 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…500mg Cefoperazone as Sodium…500mm
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision of 296th minutes: Deferred for consideration of the applications on its turn/queue.	
	Decision: Approved. **Moreover, Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore.**	

Covid Cases:

269	M/s Xenon Pharmaceutical Pvt Ltd. 9.5 Km, Sheikhupura Road, Lahore	Azocin 250 mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 11720 dated 21/05/2020 Rs. 20,000/- dated 21-05-2020 Form 5 USP Specs	As per decision of DPC of DRAP 3's 6's 10's 30's	Last inspection report is older than 3 Years.	Deferred for updated status of GMP from QA & LT.	The firm was inspected on 13-02-2020 concluding firm was advised to overcome the shortcomings and submit the compliance report to competent authorities, so that

								the inspection of the unit could be conducted accordingly for the purpose of verification thereof.

Decision of 297th meeting:
Deferred for updated status of GMP of the firm from QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
Submission by the firm:

- Copy of GMP certificate No. 66/222-DRAP(AD-021423103) dated 02-06-2022 issued on the basis of inspection conducted on 11-02-2022.
- The firm has provided alternate brand name "XEEAZO 250mg tablet".

Decision: Registration Board approved the registration of the applied product. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded in its 295th meeting.

Case No. IV: Capacity assessment

Name of Firm	M/S Welmark Pharmaceuticals
Physical Address:	Plot No.122 Block B phase v industrial estate hattar pakistan
Drug Manufacturing license No.	000614 Valid till 11-04-2022
Contact	info@welmarkpharma.com 0992617660
Date of inspection:	17th June, 2021
Purpose of inspection:	Assessment And Confirmation Of Manufacturing Capacity
Names of inspectors	1. Mr.Faisal Shehzad, Additional Director, DRAP Peshawar. 2. Mr.Atiq Ul Bari, FID DRAP Peshawar.
Names of firm's representatives:	1. Ashfaq ur Rahman (Production Manager) 2. Hamid shah (Quality Control Manager) 3. Mr.Waheed Anjum (Quality Assurance Incharge)

7. BRIEF ABOUT FIRM:

Ms. Welmark Pharmaceuticals situated at Plot No.122 Block B phase v industrial estate hattar pakistan. Was visited and inspected as per instructions contained in referred DRAP letter for the assessment of and confirmation of manufacturing surplus capacity in the following manufacturing sections:

1. Liquid Injection (General)
2. Dry Powder Injectable (General)
3. Dry Powder Injectable (Cephalosporin)

The firm was inspected in detail as per scope and relevant manufacturing; packaging and quality control records etc. for the last year were reviewed in detail and concluded accordingly. Manufacturing record/data was evaluated from January 2020 to December 2020 for the said purpose.

REGISTERED PRODUCTS		**Annexure**
Total registered products:	**349**	**A**
Registered products in aforementioned sections	**97**	**B**
Existing contract manufactured products in aforementioned sections	**36**	**C**
Registered products (Export) in aforementioned sections	**14**	

The details of Capacity calculations are as under:

Liquid Injection (General)	
Step wise capacity of General Liquid Ampoule Injection manufacturing	Capacity
Semi Auto Ampoule Washing:	
• **Per single shift** of 7 working hours (Load per Day)	**56,000 amps**

• **Per month** (23 working Days) with single shift of 7 working hours	**1,288,000 amps**
Depyrogenation Capacity (Dryer) :	
• **Per single shift** of 7 working hours (2Load per Day)	**60,000 amps**
• **Per month** (23 working Days) with single shift of 7 hours	**1,380,000 amps**
Ampoule Filling:	
• **Per single shift** of 7 working hours (Load per Day)	**52,500 amps**
• **Per month** (23 working Days) with single shift of 7hours	**1,207,500 amps**
Auto Clave:	
• **Per single shift** of 7 working hours (2Load per Day)	**50,000 amps**
• **Per month** (23 working Days) with single shift of 7 hours	**1,150,000 amps**
Packing Capacity:	
• **Per single shift** of 7 working hours (13 workers)	**28,000 amps**
• **Per month** (23working Days) with single shift of 7 hours	**644,000 amps**
Note: Limiting step in this process is Packing process for calculation Utilized Capacity	

Quarter Wise capacity utilized in General Liquid Injection Section

Quarter	Actual Production (Amps)	Capacity (Amps)	Capacity utilized in %
1st – 2020	721,500	1,932,000	37.34%
2nd – 2020	552,000	1,932,000	28.57%
3rd – 2020	1,272,600	1,932,000	65.86%
4th – 2020	910,500	1,932,000	47.12%
Total	3,456,600	7,728,000	.....
Average per Quarter	864,150	1,932,000	44.72%
Manufacturing Capacity Utilized (Average) =			***44.72%***
Manufacturing Capacity Available (Average) =			***55.28%***

SECTION WISE CAPACITY CALCULATION

Dry Powder Injectable (Cephalosporin)

Step wise capacity of General Dry Powder Injection manufacturing	Capacity
Rotary vial Washing Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,000 Vials**
• **Per month** (23 working Days) with single shift of 7 working hours	**322,000 Vials**
Depyrogenation Capacity (Dryer):	
• **Per single shift** of 7 working hours (2Load per Day)	**28,000 Vials**
• **Per month** (23 working Days) with single shift of 8 hours	**644,000 Vials**
Dry Powder Filling Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,000 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**322,000 Vials**
Vial Sealing Machine:	

• **Per single shift** of 7 working hours (Load per Day)	**14,400 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**331,200 Vials**
Packing Capacity:	
• **Per single shift** of 7 working hours (with 13 Workers)	**25,900 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**595,700 Vials**
Note: Limiting step in this process is Filling process for calculation Utilized Capacity	

Quarter Wise capacity utilized in Cephalosporin Powder Injectable Section

Quarter	Actual Production (Vials)	Capacity (Vials)	Capacity utilized in %
1st – 2020	141,350	966,000	14.632%
2nd – 2020	23,761	966,000	2.50%
3rd – 2020	171,319	966,000	17.7%
4th – 2020	187,676	966,000	19.43%
Total	524,106	3,864,000	54.262%
Average per Quarter	131,026	966,000	13.563%
Manufacturing Capacity Utilized (Average) =			***13.563%***
Manufacturing Capacity Available (Average) =			***86.427%***

SECTION WISE CAPACITY

Dry Powder Injectable (General)

Step wise capacity of General Infusion Injectable manufacturing	Capacity
Rotary vial Washing Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,000 Vials**
• **Per month** (26 working Days) with single shift of 8 working hours	**322,000 Vials**
Depyrogenation Capacity (Dryer):	
• **Per single shift** of 7 working hours (2Load per Day)	**28,000 Vials**
• **Per month** (23working Days) with single shift of 7 hours	**644,000 Vials**
Dry Powder Filling Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,000 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**322,000 Vials**
Vial Sealing Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,400 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**331,200 Vials**
Packing Capacity:	
• **Per single shift** of 7 working hours (with 13 Workers)	**25,900 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**595,700 Vials**

Note: Limiting step in this process is Filling process for calculation Utilized Capacity

Quarter Wise capacity utilized in General Powder Injectable Section			
Quarter	**Actual Production (Vials)**	**Capacity (Vials)**	**Capacity utilized in %**
1st – 2020	56,991	966,000	5.90%
2nd – 2020	57,848	966,000	5.98%
3rd – 2020	92,319	966,000	9.60%
4th – 2020	80,926	966,000	8.37%
Total	288,084	3,864,000	29.85%
Average per Quarter	72,021	234,000	7.462%

8. **Manufacturing**

Capacity Utilized (Average) = ***7.462%***

Manufacturing Capacity Available (Average) = ***92.538%***

CAPACITY OF QUALITY CONTROL DEPARTMENT

Quality Control Equipment Details							
S. #	**Equipment**	**Qty.**	**Capacity per day (tests)**	**Capacity per month (tests)**	**Max: utilization / month (tests)**	**Capacity utilization (%age)**	**Capacity available %age)**
1.	HPLC	2	4	92	69	74.5	25.5
2.	FTIR	1	20	460	29	6.15	93.85
3.	Spectrophotometer (Hitachi U-2800)	1	10	230	27	11.39	88.61
4.	Sterility Testing	Lab	4	92	13	14.17	85.83
5.	Moisture Analyser	1	50	1150	350	30.43	69.56
6.	Total Organic carbon Analyser	1	30	690	300	43.47	56.52
7.	Karl Fischer	1	30	690	129	18.69	81.30
8.	pH meter	1	50	1150	130	11.30	88.7
9.	Conductivity Meter	1	50	1150	380	33.04	66.96
10.	Weighing balance	1	50	1150	510	44.34	55.65
11.	Liquid particle Counter	1	29	667	380	57	43
12.	Hot incubator	1	50	1150	350	30.34	69.56
13.	Cool incubator	1	50	1150	350	30.34	69.56
14.	Convection Oven	1	50	1150	610	53.04	46.95
15.	Autoclave	1	10	230	125	54.34	45.65
16.	Weighing balance	1	50	1150	510	44.34	55.65

CAPACITY OF STERILE DRY POWDER INJECTION (GENERAL)

Welmark Pharmaceuticals Registration	Welmark Pharmaceuticals Export Registration	Welmark Pharmaceuticals Pending Applications	Contract Products Registrations	Contract products Pending Applications
14	0	0	8	5

CAPACITY OF STERILE INJECTABLE LIQUID AMPOULE (GENERAL)

Welmark Pharmaceuticals Registration	Welmark Pharmaceuticals Export Registration	Welmark Pharmaceuticals Pending Applications	Contract Products Registrations	Contract products Pending Applications
41	0	5	9	7

CAPACITY OF DRY POWDER INJECTABLE (CEPHALOSPORIN)

Welmark Pharmaceuticals Registration	Welmark Pharmaceuticals Export Registration	Welmark Pharmaceuticals Pending Applications	Contract Products Registrations	Contract products Pending Applications
42	0	0	21	3

9. CONCLUSIO N:

Production and QC capacity utilized and available is summarized below:

Section name	Manufacturer total registrations	Pending application for registration	Contract product registration	Contract products pending application	Manufacturing capacity utilized (average)	Manufacturing capacity available (average)
Sterile Injectable Liquid Ampoule (General)	41	05	09	07	44.72%	55.28%
Sterile Dry Powder Injectable (General)	14	0	08	05	7.462%	92.538%
Sterile Dry Powder Injectable (Cephalosporin)	42	0	21	03	13.563%	86.427%

10. QC Department

S.No	Equipment	Capacity Available (%)
1.	HPLC	25.5
2.	FTIR	93.85
3.	Spectrophotometer (Hitachi U-2800)	88.61
4.	Sterility Testing	85.83
5.	Moisture Analyser	69.56
6.	Total Organic carbon Analyser	56.52
7.	Karl Fischer	81.30
8.	pH meter	88.7
9.	Conductivity Meter	66.96
10.	Weighing balance	55.65
11.	Liquid particle Counter	43
12.	Hot incubator	69.56
13.	Cool incubator	69.56
14.	Convection Oven	46.95
15.	Autoclave	45.65
16.	Weighing balance	55.65

Based on the people met, documents reviewed and observations made during the detailed inspection, M/S Welmark Pharmaceuticals situated at Plot No.122 Block B phase v industrial estate hattar pakistan, has **ample surplus capacity** in the manufacturing and quality control laboratory for the purpose of manufacturing on contract basis as summarized above.

11. SIGNATURES OF INSPECTORS

FIRM'S REPRESENTATIVES	INSPECTOR
Mr. Ashfaq ur Rahman (Production Manager)	**Mr. Faisal Shehzad,** Additional Director, DRAP Peshawar.
Mr. Hamid Shah (Quality Control Manager)	**Mr. Atiq Ul Bari** FID DRAP, Peshawar.
Mr. Waheed Anjum (QualityAssurance In-Charge)	

Decision: Registration Board deliberated upon the above presented capacity assessment report of M/s Welmark Pharmaceuticals and referred the case back to the panel for confirmation of follwoing from the firm:

i. **No. of registered products of M/s Welmark Pharmaceuticals being analysed on HPLC.**
ii. **No. of registered products of M/s Welmark Pharmaceuticals having pharmacopoeial monographs but are being tested on in-house methods.**

Moreover, Keeping in view already registered products and present testing capacity, the Board directed M/s Welmark Pharmaceuticals to add 02 more HPLC systems in their Quality Control laboratory.

Registration Board deferred following cases of contract manufacturing from M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan till compliance of above cited points.

270.		
	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Anmol 40mg Injection
	Composition	Each Vial Contains: Omeprazole sodium (Iyophilized powder) …40mg
	Diary No. Date of R& I & fee	Dy. No. 40718: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial. TGA approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	**Applicant**: could not be confirmed. **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	• The firm has applied for Omeprazole as sodium (as per master formula). The firm revised Omeprazole to Omeprazole sodium in the label claim. • The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. • Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295th meeting deferred the case for submission of fee for revision of formulation and capacity assessment of m/s welmark.
	Evaluation by PEC	• The firm submitted the capacity assessment report as presented above. • The firm did not submit the fee for revision of formulation.
	Decision of 312th Meeting: deferred for the following: • latest gmp inspection report of m/s roryan pharmaceuticals conducted in the last three years. • latest gmp inspection report of m/s welmark pharmaceuticals conducted in the last three years. • capacity assessment of m/s welmark pharmaceuticals on the prescribed proforma. • submission of fee for revision of salt form. **submission by the firm:** • copy of GMP certificate of m/s Roryan pharmaceuticals pvt ltd. no. f.11-52/2022-drap-71 dated 17th June 2022 issued on the basis of inspection conducted on 13/01/2022. • copy of GMP certificate no. f.11-96/2021-drap-97 dated 23/11/2021 issued on the basis of inspection conducted on 11/11/2021. • the firm has submitted full fee Rs. 75,000/- for revision of formulation from omeprazole sodium 40mg to omeprazole as sodium 40mg vide challan number 29997310489 dated 04/07/2022. Label claim: Each Vial Contains: Omeprazole sodium …40mg	

	(Iyophilized powder)	
271.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Irosuc 20mg/ml Injection
	Composition	Each injection contains: Iron sucrose …20mg
	Diary No. Date of R& I & fee	Dy. No. 40713: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml ampule x 5's, As per SRO
	Approval status of product in Reference Regulatory Authorities	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	**Applicant**: could not be confirmed. **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	• The firm revised 'iron sucrose' to 'iron (III)-hydroxide-sucrose eq. to elemental iron' without submission of applicable fee. • Adjustment of weight of API as per salt factor is required in master formula. • Proof of international availability of same formulation, same strength and same filled volume in reference regulatory authorities as defined in 275th meeting of the registration board is required. Otherwise, revise the strength in line with the reference product along with submission of applicable fee. • The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. • Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295th meeting deferred the case for; • Submission of fee for revision of formulation • Adjustment of weight of API in the master formulation • capacity assessment of m/s Welmark
	Evaluation by PEC	• The firm submitted the capacity assessment report as presented above. • The TGA Australia has mentioned iron sucrose as synonym for iron (III)-hydroxide-sucrose. The board may look into the matter of fee. • Adjustment of weight of API as per salt factor is required in master formula.
	Decision of 312th meeting: Deferred for the following • Latest GMP inspection report of M/s Roryan Pharmaceuticals conducted in the last three years. • Latest GMP inspection report of M/s Welmark Pharmaceuticals conducted in the last three years. • Capacity assessment of M/s Welmark Pharmaceuticals on the prescribed proforma. • Adjustment of weight of API as per salt factor is required in master formula along with submission of applicable fee. submission by the firm: • copy of GMP certificate of m/s Roryan pharmaceuticals pvt ltd. no. f.11-52/2022-drap-71 dated 17th June 2022 issued on the basis of inspection conducted on 13/01/2022. • copy of GMP certificate no. f.11-96/2021-drap-97 dated 23/11/2021 issued on the basis of inspection conducted on 11/11/2021.	

	• The firm has submitted full fee Rs. 75,000/- for revision of formulation from Iron Sucrose to Iron (III) hydroxide Sucrose Eq. to elemental Iron 100mg per ampoule (5mL) vide challan number 94055850266 dated 04/07/2022 along with the revised master formula. Label Claim: Each Ampoule (5mL) contains: Iron (III) hydroxide sucrose complex Eq. to Elemental Iron……100mg	
272.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Mospro 80mg/ml Injection
	Composition	Each injection contains: Artemether…80mg
	Diary No. Date of R& I & fee	Dy. No. 40715: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Artemisinin and derivatives, plain
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Artemether 80mg/ml solution for injection (1ml). PMDA approved
	Me-too status	Malasan Injection (1ml). Reg. No. 30366
	GMP status	**Applicant**: could not be confirmed. **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	• The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. • Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295th meeting deferred the case for capacity assessment of m/s welmark.
	Evaluation by PEC	The firm submitted the capacity assessment report as presented above.
	Decision of 312th meeting: Deferred for the following: • Latest GMP inspection report of M/s Roryan Pharmaceuticals conducted in the last three years. • Latest GMP inspection report of M/s Welmark Pharmaceuticals conducted in the last three years. • Capacity assessment of M/s Welmark Pharmaceuticals on the prescribed proforma. submission by the firm: • copy of GMP certificate of m/s Roryan pharmaceuticals pvt ltd. no. f.11-52/2022-drap-71 dated 17th June 2022 issued on the basis of inspection conducted on 13/01/2022. • copy of GMP certificate no. f.11-96/2021-drap-97 dated 23/11/2021 issued on the basis of inspection conducted on 11/11/2021.	
273.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	ME LOXIT 500mg Injection
	Composition	Each ml contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy. No. 40714: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Mecobalamin injection 500µg (1ml). PMDA approved
	Me-too status	Balco 500mcg IM/IV Injection (1ml). Reg. No. 81484

	GMP status	**Applicant**: could not be confirmed. **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	• The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. • Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295th meeting deferred the case for capacity assessment of m/s welmark.
	Evaluation by PEC	The firm submitted the capacity assessment report as presented above.
	Decision of 312th meeting: Deferred for the following: • Latest GMP inspection report of M/s Roryan Pharmaceuticals conducted in the last three years. • Latest GMP inspection report of M/s Welmark Pharmaceuticals conducted in the last three years. • Capacity assessment of M/s Welmark Pharmaceuticals on the prescribed proforma. submission by the firm: • copy of GMP certificate of m/s Roryan pharmaceuticals pvt ltd. no. f.11-52/2022-drap-71 dated 17th June 2022 issued on the basis of inspection conducted on 13/01/2022. • copy of GMP certificate no. f.11-96/2021-drap-97 dated 23/11/2021 issued on the basis of inspection conducted on 11/11/2021.	

Agenda of Evaluator PEC-II

Case no. 01 New Registration applications on Form 5F (Human)
a. New Cases (Human)

274.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on basis of inspection conducted on 09-03-2020
	Evidence of approval of manufacturing facility	GMP certificate issued on basis of inspection conducted on 09-03-2020 declares availability of Liquid injection ampoule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32574 dated 30-11-2021
	Details of fee submitted	Rs.30,000/- dated 17-11-2021
	The proposed proprietary name / brand name	**Cara-C 10mg/5ml IV Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Cisatracurium Besylate Eq. to Cisatracurium…2mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Neuromuscular blocking agent
	Reference to Finished product specifications	USP specification
	Proposed Pack size	5's
	Proposed unit price	--
	The status in reference regulatory authorities	"NIMBEX Injection" Approved by US FDA
	For generic drugs (me-too status)	CIS-CURON 2mg/ml Injection (Reg.# 088248) of m/s Brookes Pharma
	Name and address of API manufacturer.	M/s Lianyungang Guike Pharmaceutical, nO. 1, Xianfeng road, Dapu industry zone, Economic & Technical Devleopment area, Lianyugang city, Jiangsu, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 6°C ± 2°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the comparator product of Cis-Curon injection of M/s Brookes Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA	
Manufacturer of APIs	M/s Lianyungang Guike Pharmaceutical, nO. 1, Xianfeng road, Dapu industry zone, Economic & Technical Devleopment area, Lianyugang city, Jiangsu, China
API Lot No.	YF002210101

Description of Pack (Container closure system)	5ml, Type I , transparent glass ampoule.		
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 25°C ± 2°C / 60% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-014	T-015	T-016a
Batch Size	213 ampoules	213 ampoules	213 ampoules
Manufacturing Date	April-2021	April-2021	April-2021

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (Certificate# JS20160594) issued by China Food & Drug Administration valid upto 12-01-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Islamabad, has been submitted dated 04-03-2021for import of 10.0gm of Cisatracurim besylate..
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

Section#	Observtaion	Firm's response
3.2.S.4.3	Performance of precession parameter shall be submitted in analytical method verification studies.	• Submitted
3.2.P.2.2.1	Submit details i.e., brand name, manufacturer, of the reference product against which Pharmaceutical equivalence has been performed.	• Firm has submitted following detail of reference product used against pharmaceutical equivalence having following information: • Brand Name: CIS-CURON INJECTION • Manufacturer: M/s Brooks Pharmaceuticals Labs (pvt) Karachi. • Reg# 088248
3.2.P.8	• Valid GMP certificate of drug substance manufacturer issued by the relevant regulatory authority shall be submitted. • Submit details of minimum handling capacity of compounding vessel used for manufacturing of stability batches.	Firm has submitted DML# 20160305 issued by NMPA valid upto 26-09-2025. Conical flask having capacity of 2.0 litrs with graduation marks was used during manufacturing of stability batches having minimum capscity of 0.1Ltr. Firm has submitted details of no. of samples required for each time point of stability studies

	• Justify the proposed batch size against the no. of units required to complete accelerated stability studies (6 months) and long term stability studies till claimed shelf life.	wherein batch size has been justified for the performance of complete long term stability studies.	

Decision: Approved.

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

275.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-19/2014-Lic. from Secretary CLB for issuance of DML, declaring availability of "tablet general section".
	Dy. No. and date of submission	Dy.No 33039 dated 16-12-2021
	Details of fee submitted	Rs.30,000/- dated 01-12-2021
	The proposed proprietary name / brand name	**Celezib 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Celecoxib ……100mg
	Pharmaceutical form of applied drug	Clear and colorless solution filled in clear glass ampoules with red and blue ACF rings and blue color OPC mark
	Pharmacotherapeutic Group of (API)	Non-steroidal Anti inflammatory (NSAID)
	Reference to Finished product specifications	BP
	Proposed Pack size	20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Celecoxib 100 mg capsules, hard by M/s Macleods Pharma UK Limited, approved by MHRA of UK.
	For generic drugs (me-too status)	Celbex 100mg capsule by M/s Getz Pharma (Pvt) Limited Reg. No. 028694
	GMP status of the Finished product manufacturer	New DML was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 29-08-2018, including Capsule general section

	Name and address of API manufacturer.	M/s AARTI DRUGS LIMITED, Plot No. E-21/22, M.I.D.C, Tarapur, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches:(KM-1102215, KM-1102315, KM-1102415)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Comparative dissolution profile has been established against the Clebex capsule of M/s Getz Pharma in three buffer mediums i.e., ph1.2, pH 4.5 & ph 6.8 with acceptable results.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

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

Batch Size	2000 capsules	2000 capsules	2000 capsules
Manufacturing Date	12-2020	07-2021	07-2021
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.6.5	Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufacturer.	Submitted GMP certificate is of another site of AARTI drugs ltd (PLOT NO. W-60(B)W-61(B)W-62(B)W-71(B)W-72(B)W-73(B),MIDC, Tarapur Thane, India), instead of the site (Plot No. E-21/22, M.I.D.C, Tarapur, Maharashtra, India) from which drug substance has been imported.
3.2.S.6	Drug substance is of USP standard whereas reference standard of BP grade has been submitted.	As the drug substance is available in both USP and BP and have same specifications and analytical procedure. Drug product is available only in BP so we chosen BP standard and used it for analysis.
3.2.P.2.2.1	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted.	• Firm has submitted Pharmaceutical equivalence report against the Celebrex capsule of M/s Getz, wherein instead of dissolution test of batch release, CDP study results have been submitted.
3.2.P.3.5	Submitted process validation protocol does not include sampling plan.	Process validation protocol including sampling plan has been submitted.
3.2.P.8.3	• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	• Firm has submitted copy of commercial invoice# SAMP/1002//20-21-23/10/2020

		• Raw data sheets for complete stability studies shall be submitted. • Submitted analytical record does not reflect the performance of system suitability test during Assay analysis as recommended by BP monograph of Celcoxib capsules.	frrom M/s AARTI drugs ltd., in the name of islam Pharma for the 2.5 Kg of Celecoxib. The submitted invoice is not attested by DRAP I&E office. • Firm has also submitted copy of Air WayBill. • Firm has performed system suitability test by establishing the RSD of standard replicates, while BP monograph recommends performance of system suitability with the help of impurity standards.

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

276.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25216 Dated 10-09-2021
	Details of fee submitted	PKR 30,000/-: Dated 07-07-2021
	The proposed proprietary name / brand name	Tamadol 50mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Tramadol hydrochloride ……..…… 50mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Opioid Analgesic ATC code: N02AX02
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	10’s , 20’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zydol 50mg capsule of Grunenthal (MHRA approved).
	For generic drugs (me-too status)	Tonoflex 50mg Capsule of M/s Sami pharma
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 09-06-2020.
	Name and address of API manufacturer.	M/s Supriya Life science Ltd, A-5/2 Lote parshuram Industrial Area, M.I.D.C, Tal-khed, Dist, Ratnigiri 415772, Maharashtra state, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C±2°C/65% ± 5%RH for 24 months Accelerated:40°C±2°C/75% ± 5%RH for 6 months Batches: T-001, T-002, T-003.
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Tonoflex capsule 50mg (Batch # 007F) by M/s Sami Pharmaceuticals by performing Moisture content, Disintegration time, dissolution, Assay. CDP has been performed against the same brand that is in Acid media (pH 1.0-1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Supriya Life Science Ltd, A-5/2 Lote parshuram Industrial Area, M.I.D.C, Tal-khed, Dist, Ratnigiri 415772, Maharashtra state, India.
API Lot No.	SLL/TDM/0120001
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T-001	T-002	T-003
Batch Size	5000 capsules	7500 capsules	7500 capsules
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation			
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued by Food and Drug Administration, Maharashtra state, India valid 04-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice specifying import of 200Kgs of Tramadol hydrochloride cleared by Assistant Director (I & E), Lahore dated 07-02-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers.

Remarks of Evaluator:

Section#	Observations	Firm's response
1.6.5	Valid GMP certificate of the drug substance manufacturer shall be submitted.	The firm has submitted copy of GMP certificate# NEW-WHO-GMP/CERT/KD/103995/2021/11/38094 issued by Food and Drug Administration, Maharashtra state, India valid 23-11-2024.
3.2.S.8.3	Complete raw data sheets for the performance of dissolution test during stability studies shall be submitted.	Firm has submitted analytical record including raw data sheets for the performance of dissolution test.

Decision: Approved.

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

277.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited 30 km, Multan Road, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24064 dated 01-09-2021
	Details of fee submitted	Rs.75,000/- dated 30-07-2021
	The proposed proprietary name / brand name	**Trilin 5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated extended-release tablet contains: Empagliflozin …….. 5mg Linagliptin …… 2.5 mg (as immediate release coating) Metformin HCl …… 1000mg (as extended release core)
	Pharmaceutical form of applied drug	Film-coated extended-release tablet
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** sodium-glucose co-transporter 2 (SGLT2) inhibitors **Linagliptin:** dipeptidyl peptidase-4 (DPP-4) inhibitors **Metformin HCl:** antihyperglycemic drug
	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy® XR Tablets by M/s Boehringer Ingelheim, FDA Approved.
	For generic drugs (me-too status)	Not Available
	Evidence of manufacturing facility	GMP certificate granted on basis of inspection conducted on 18.06.2020 endorses tablet general section.
	GMP status of the Finished product manufacturer	GMP certificate granted on basis of inspection conducted on 18.06.2020.
	Name and address of API manufacturer.	**Linagliptin:** **M/s Lee Pharma Limited, India** HuaiNan ShunLong Pharmaceutical CO, LTD. No. 9 Yongxing Road, Econonmic and Technological Development Development Zone, Huainan City, Anhui Province China. **Empagliflozin:** HuaiNan ShunLong Pharmaceutical CO, LTD. No. 9 Yongxing Road, Econonmic and Technological Development Development Zone, Huainan City, Anhui Province China. **Metformin Hydrochloride:** Shandong Keyuan Pharmaceutical Co., Ltd. Keyuan Street, Shandong shanghe Economic Zone, Jinan city, Shandong Province, China

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies of Drug substance	**Empagliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Linagliptin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Metformin HCl:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Trijardy XR Tablets approved by US-FDA. CDP has been performed against the same brand that is Trijardy XR Tablets 12.5/2.5/1000mg approved by US-FDA inAcid media (pH 1.2) , Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.
STABILITY STUDY DATA		
Manufacturer of API	**Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China **Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China **Metformin Hydrochloride:**	

	M/s Auro Laboratories Ltd., K-56, MIDC tarapur, Boiser, Dist, Thane, Maharashtra, India.		
API Lot No.	**Empagliflozin:** L-E-202000409-D01-E06-01 **Linagliptin:** L-20200219-D01-L09-01 **Metformin HCl:**		
Description of Pack (Container closure system)	Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TLM00110P	TLM00210P	TLM00310P
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	10-2020	10-2020	10-2020
No. of Batches	02		

278.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited 30 km, Multan Road, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30929 dated 11-11-2021
	Details of fee submitted	Rs.75,000/- dated 30-07-2021
	The proposed proprietary name / brand name	**Trilin 10/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated extended-release tablet contains: Empagliflozin …….. 10mg Linagliptin …… 5 mg (as immediate release coating) Metformin HCl …… 1000mg (as extended release core)
	Pharmaceutical form of applied drug	Film-coated extended-release tablet
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** sodium-glucose co-transporter 2 (SGLT2) inhibitors **Linagliptin:** dipeptidyl peptidase-4 (DPP-4) inhibitors **Metformin HCl:** antihyperglycemic drug
	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Trijardy® XR Tablets by M/s Boehringer Ingelheim, FDA Approved.
	For generic drugs (me-too status)	Not Available
	Evidence of manufacturing facility	GMP certificate granted on basis of inspection conducted on 18.06.2020 endorses tablet general section.
	GMP status of the Finished product manufacturer	GMP certificate granted on basis of inspection conducted on 18.06.2020.
	Name and address of API manufacturer.	**Linagliptin:** **M/s Lee Pharma Limited, India** HuaiNan ShunLong Pharmaceutical CO, LTD. No. 9 Yongxing Road, Econonmic and Technological Development Development Zone, Huainan City, Anhui Province China. **Empagliflozin:** HuaiNan ShunLong Pharmaceutical CO, LTD. No. 9 Yongxing Road, Econonmic and Technological Development Development Zone, Huainan City, Anhui Province China. **Metformin Hydrochloride:** Shandong Keyuan Pharmaceutical Co., Ltd. Keyuan Street, Shandong shanghe Economic Zone, Jinan city, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies of Drug substance	**Empagliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Linagliptin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Metformin HCl:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Trijardy XR Tablets 25/25/1000mg approved by US-FDA. CDP has been performed against the same brand that is Trijardy XR Tablets 12.5/2.5/1000mg approved by US-FDA in Acid media (pH 1.2) , Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	**Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China **Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China **Metformin Hydrochloride:** M/s Auro Laboratories Ltd., K-56, MIDC tarapur, Boiser, Dist, Thane, Maharashtra, India.		
API Lot No.	**Empagliflozin:** L-E-202000409-D01-E06-01 **Linagliptin:** L-20200219-D01-L09-01 **Metformin HCl:**		
Description of Pack (Container closure system)	Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TEL00110P	TEL 00210P	TEL 00310P
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	10-2020	10-2020	10-2020
No. of Batches	02		

279.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited 30 km, Multan Road, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 31873 dated 19-11-2021
	Details of fee submitted	Rs.75,000/- dated 30-07-2021
	The proposed proprietary name / brand name	**Trilin 25/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated extended-release tablet contains: Empagliflozin …….. 25mg Linagliptin …… 5 mg (as immediate release coating) Metformin HCl …… 1000mg (as extended release core)
	Pharmaceutical form of applied drug	Film-coated extended-release tablet
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** sodium-glucose co-transporter 2 (SGLT2) inhibitors **Linagliptin:** dipeptidyl peptidase-4 (DPP-4) inhibitors **Metformin HCl:** antihyperglycemic drug
	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy® XR Tablets by M/s Boehringer Ingelheim, FDA Approved.
	For generic drugs (me-too status)	Not Available
	Evidence of manufacturing facility	GMP certificate granted on basis of inspection conducted on 18.06.2020 endorses tablet general section.
	GMP status of the Finished product manufacturer	GMP certificate granted on basis of inspection conducted on 18.06.2020.
	Name and address of API manufacturer.	**Linagliptin:** **M/s Lee Pharma Limited, India** HuaiNan ShunLong Pharmaceutical CO, LTD. No. 9 Yongxing Road, Econonmic and Technological Development Development Zone, Huainan City, Anhui Province China. **Empagliflozin:** HuaiNan ShunLong Pharmaceutical CO, LTD. No. 9 Yongxing Road, Econonmic and Technological Development Development Zone, Huainan City, Anhui Province China. **Metformin Hydrochloride:** Shandong Keyuan Pharmaceutical Co., Ltd. Keyuan Street, Shandong shanghe Economic Zone, Jinan city, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure,

		general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies of Drug substance	**Empagliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Linagliptin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Metformin HCl:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Trijardy XR Tablets 10/5/1000mg approved by US-FDA. CDP has been performed against the same brand that is Trijardy XR Tablets 12.5/2.5/1000mg approved by US-FDA in Acid media (pH 1.2) , Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	**Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China **Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China **Metformin Hydrochloride:** M/s Auro Laboratories Ltd., K-56, MIDC tarapur, Boiser, Dist, Thane, Maharashtra, India.
API Lot No.	**Empagliflozin:** L-E-202000409-D01-E06-01 **Linagliptin:** L-20200219-D01-L09-01 **Metformin HCl:**
Description of Pack (Container closure system)	Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 03 months Accelerated: 03 months
Frequency	Accelerated: 0, 3, 6 (Months)

		Real Time: 0, 3, 6 (Months)		
Batch No.		TML00110P	TML 00210P	TML 00310P
Batch Size		5000 tab	5000 tab	5000 tab
Manufacturing Date		10-2020	10-2020	10-2020
No. of Batches		02		
280.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited 30 km, Multan Road, Lahore, Pakistan**		
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales		
	Dy. No. and date of submission	Dy.No 31874 dated 19-11-2021		
	Details of fee submitted	Rs.75,000/- dated 30-07-2021		
	The proposed proprietary name / brand name	**Trilin 12.5/2.5/1000 mg Tablet**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated extended-release tablet contains: Empagliflozin …….. 12.5mg Linagliptin …… 2.5 mg (as immediate release coating) Metformin HCl …… 1000mg (as extended release core)		
	Pharmaceutical form of applied drug	Film-coated extended-release tablet		
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** sodium-glucose co-transporter 2 (SGLT2) inhibitors **Linagliptin:** dipeptidyl peptidase-4 (DPP-4) inhibitors **Metformin HCl:** antihyperglycemic drug.		
	Reference to Finished product specifications	In-House		
	Proposed Pack size	8 x 4's		
	Proposed unit price	As per SRO		
	The status in reference regulatory authorities	Trijardy® XR Tablets 12.5mg/2.5mg/1000mg by M/s Boehringer Ingelheim, FDA Approved.		
	For generic drugs (me-too status)	Not Available		
	Evidence of manufacturing facility	GMP certificate granted on basis of inspection conducted don 07-03-02019 declares availability of tablet general section.		
	GMP status of the Finished product manufacturer	GMP certificate granted on basis of inspection conducted don 07-03-02019.		

	Name and address of API manufacturer.	**Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China **Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China **Metformin Hydrochloride:** M/s Auro Laboratories Ltd., K-56, MIDC tarapur, Boiser, Dist, Thane, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies of Drug substance	**Empagliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Linagliptin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Metformin HCl:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Trijardy XR Tablets 12.5/2.5/1000mg approved by US-FDA. CDP has been performed against the same brand that is Trijardy XR Tablets 12.5/2.5/1000mg approved by US-FDA inAcid media (pH 1.2) , Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.
STABILITY STUDY DATA		

<table>
<tr><td>Manufacturer of API</td><td colspan="3">Linagliptin:
M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China
Empagliflozin:
M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China
Metformin Hydrochloride:
M/s Auro Laboratories Ltd., K-56, MIDC tarapur, Boiser, Dist, Thane, Maharashtra, India.</td></tr>
<tr><td>API Lot No.</td><td colspan="3">Empagliflozin: L-E-202000409-D01-E06-01
Linagliptin: L-20200219-D01-L09-01
Metformin HCl:</td></tr>
<tr><td>Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton</td></tr>
<tr><td>Stability Storage Condition</td><td colspan="3">Real time: 30˚C ± 2˚C / 65% ± 5%RH
Accelerated: 40˚C ± 2˚C / 75% ± 5%RH</td></tr>
<tr><td>Time Period</td><td colspan="3">Real time: 03 months
Accelerated: 03 months</td></tr>
<tr><td>Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td>Batch No.</td><td>TLE0010P</td><td>TLE0020P</td><td>TLE0030P</td></tr>
<tr><td>Batch Size</td><td>5000 tablets</td><td>5000 tablets</td><td>5000 tablets</td></tr>
<tr><td>Manufacturing Date</td><td>10-2020</td><td>10-2020</td><td>10-2020</td></tr>
<tr><td>No. of Batches</td><td colspan="3">02</td></tr>
<tr><td colspan="4">Documents submitted along with stability data</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="2"></td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="2">• Copy of DML (Certificate# Liao20150233) issued by Liaoning FDA, valid upto 20-12-2022 for M/s Fuxin Long Rui
• Firm had provided copy of GMP certificate (NEW-WHO-GMP/CERT/KD/17230/2015/11/10384) issued by Food & Drug Administration Maharashtra, India valid upto: 18-04-2017</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="2">Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted.
Empagliflozin:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>L-E-202000409-D01-E06-01</td><td>SY200061201</td><td>0.35kgs</td><td>20-06-2020</td></tr>
</table>
4 <u>Linagliptin:</u>
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>L-20200219-</td><td>SY200714-F</td><td>0.125kgs</td><td>28-07-2020</td></tr>
</table></td></tr>
</table>

		D01-L09-01
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	--
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Digital data logger record has been submitted for temperature & humidity conditions of both accelerated and long-term stability chambers.

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.3	Valid GMP inspection report shall be submitted for M/s Pacific Pharmaceuticals, 30-Km, Multan Road, Lahore.	GMP certificate submitted issued on basis of inspection conducted on 14-09-2021
1.6.5	Valid GMP certificate of M/s Auro laboratories, shall be submitted.	Firm has submitted Certificate No: ES/083/15 issued by AEMPS of Spain, valid upto April, 2017. Submitted GMP certificate is still not valid.
3.2.S.4.1	Justification shall be submitted for the test of optical rotation of Empagliflozin.	It is tested as per supplier specifications.
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted for Empagliflozin & Linagliptin.	Submitted.
3.2.P.2.1	• Innovator product has used Polyethylene oxide as extended release polymer, whereas you have used HPMC 15000 for the same purpose. Justification shall be submitted for this variation along with drug excipient compatibility study. • Dissolution limits defined in the "Quality Target product Profile" are different from that recommended by US FDA for the Innovator product i.e., Trijardy XR tablets.	• Composition is according to innovator, Product is stable, no variations in result observed were found during all study. • Compatibility study report has been submitted. • Dissolution Limits in CDP are updated according to USFDA and updated Protocol, Report has been submitted.
3.2.P.5.1	• Submitted drug product specifications does not include test for "Uniformity of Dosage Unit" by way of content uniformity for Empagliflozin & Linagliptin. • Dissolution time points for metformin HCl & Linagliptin are not as recommended by US FDA for the	Firm has submitted revised drug product specification including test of content uniformity whereas the dissolution specifications for Empagliflozin & Linagliptin are still not as recommended by US FDA for innovator product. Firm has proposed dissolution limits of

	innovator product i.e., Trijardy XR tablets.	NLT Q in 60 minutes for both Empagliflozin & Linagliptin whereas US FDA has recommended 45 minutes & 30 minutes time point for Empagliflozin & Linagliptin respectively.
3.2.P.5.2	• Submitted analytical procedure for dissolution test does not mention details for standard solution preparation. • Standard concentration for each API does not equate with the sample concentrations in the analytical procedure of Assay test.	Firm has revised analytical procedure for the details of standard solution preparation and concentration of standard and sample solution, whereas the stability data had been submitted as per previous method.
3.2.P.5.3	The concentration range applied for the linearity test of Linagliptin, does not cover the specified concertation for Assay test.	Revised method validation report has been submitted.
3.2.P.5.4	Submitted Batch analysis COA does not include test of content uniformity for Empagliflozin & Linagliptin. Dissolution time points for Linagliptin & Metformin HCl are not as recommended by US FDA for the innovator product i.e., Trijardy XR tablets.	Firm has submitted revised drug product specification including test of content uniformity whereas the dissolution specifications for Empagliflozin & Linagliptin are still not as recommended by US FDA for innovator product. Firm has proposed dissolution limits of NLT Q in 60 minutes for both Empagliflozin & Linagliptin whereas US FDA has recommended 45 minutes & 30 minutes time point for Empagliflozin & Linagliptin respectively.
3.2.P.6	• Submitted COA of working standard of Metformin HCl declares retest date as May 2021, whereas stability studies have also been performed subsequent to this date. • Submitted COA of working standard of Empagliflozin declares retest date as March 2021, whereas stability studies have also been performed subsequent to this date.	No justification has been submitted.
3.2.P.8.3	• Documents confirming import of Metformin HCl shall be submitted. • Analytical record i.e., raw data sheets, chromatograms & COAs shall be submitted for complete stability studies at both accelerated and long-term conditions. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	• Firm has submitted commercial invoice attested by AD DRAP I&E, Lahore 11-12-2018 for import of 1000Kg Metformin HCl. • Firm has submitted raw data sheet for the stability studies. • Audit trail reports on product testing have not been submitted. • Details of data logger have been submitted.
• Submit clarification regarding not ensuring the dissolution profile at in-process stage of Metformin		Not replied.

HCl extended release core prior to proceeding for Active coating of other drug substances. • Submitted BMR declare dispensing of Empagliflozin & Linagliptin as per 100% content of desired label claim. Justification shall be submitted that how dispensed quantity will produce 100% content of Empagliflozin & Linagliptin, when both APIs are being included by way of Active coating and how the wastage of coating solution will be compensated.	Firm has submitted a document titled "Additional Raw/Packaging materials Requisition Form" 01-10-2020 wherein dispensing of Empagliflozin & Linagliptin for batch# 00110P,00210P,003 has been declared with the reason as "To produce 100% content of Empagliflozin & Linagliptin, overages required for coating solution.

Decision: Registration Board deferred the applications of Trilin 12.5/2.5/1000 mg Tablet, Trilin 25/5/1000 mg Tablet, Trilin 10/5/1000 mg Tablet & Trilin 5/2.5/1000 mg Tablet for following:

- **Valid GMP certificate of M/s Auro Laboratories Ltd., K-56, MIDC tarapur, Boiser, Dist, Thane, Maharashtra, India, shall be submitted.**
- **Dissolution specifications for Empagliflozin & Linagliptin are not as recommended by US FDA for innovator product. Firm has proposed dissolution limits of NLT Q in 60 minutes for both Empagliflozin & Linagliptin whereas US FDA has recommended 45 minutes & 30 minutes time point for Empagliflozin & Linagliptin respectively. Justification shall be submitted in this regard.**
- **Submitted COA of working standard of Metformin HCl declares retest date as May 2021, whereas stability studies have also been performed subsequent to this date. Justification shall be submitted in this regard.**
- **Submitted COA of working standard of Empagliflozin declares retest date as March 2021, whereas stability studies have also been performed subsequent to this date. Justification shall be submitted in this regard.**
- **Submit clarification regarding not ensuring the dissolution profile at in-process stage of Metformin HCl extended release core prior to proceeding for Active coating of other drug substances.**
- **Submit batch wise details of each strength for the dispensing of Linagliptin & Empagliflozin for ensuring the 100% content as per label claim.**
- **HPLC chromatograms shall be submitted for complete stability studies of each strength.**
- **Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.**

281.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals, PVT, Ltd., 581-Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27810 dated 07-10-2021
	Details of fee submitted	Rs.75,000/- dated 27-09-2021
	The proposed proprietary name / brand name	**Tazit 2.25gm Sterile Dry Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium Equivalent to Piperacillin ……. 2.0 g Tazobactam Sodium Equivalent to Tazobactam ……. 0.25 g

	Pharmaceutical form of applied drug	Intravenous Sterile Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	First Generation Beta Lactam Antibiotics (Penicillin)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tanzo 2.25 g Injection by M/s Bosch, Reg. No. 039593
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 22-09-2020, wherein Dry powder injectable Penicillin section is declared.
	Name and address of API manufacturer.	M/s Shandong /Anxin Pharmaceutical Co., Ltd. 849, Dongjia Town, Licheng District, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Tanzo 4.5 g Injection by M/s Bosch Pharma by performing quality tests (Identification, Assay and Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted
STABILITY STUDY DATA		

Manufacturer of API		M/s Shandong /Anxin Pharmaceutical Co., Ltd. 849, Dongjia Town, Licheng District, Jinan, Shandong, China		
API Lot No.		KA1007150016		
Description of Pack (Container closure system)		Glass Vial with rubber stopper sealed with flip off seal and packed in unit carton (1×1's)		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 24 months Accelerated: 6 months		
Frequency		Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.		N5001	N5002	N5003
Batch Size		42,50 vials	41,60 vials	63,80 vials
Manufacturing Date		03-2015	03-2015	04-2015
Date of Initiation		25-05-2015	26-05-2015	12-06-2015
No. of Batches		03		
Documents submitted along with stability data.				
	Reference of previous approval of applications with stability study data of the firm (if any)	--		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2018001 issued by Shandong Food and Drug Administration valid till 24/07/2023.		
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD DRAP I&E, Lahore dated 11-02-2015 for import of 100Kg of Piperacillin sodium: Tazobactam sodium (8:1)		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	N/A		
282.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi**		
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals, PVT, LTD. 581-Sundar Industrial Estate, Raiwind Road Lahore, Punjab 54000.		
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales		

	Dy. No. and date of submission	Dy. No 27811 dated 07-10-2021
	Details of fee submitted	Rs.75,000/- dated 27-09-2021
	The proposed proprietary name / brand name	**Tazit 4.5gm Sterile Dry Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium USP Equivalent to Piperacillin ……. 4.0 g Tazobactam Sodium USP Equivalent to Tazobactam ……. 0.50 g
	Pharmaceutical form of applied drug	Intravenous Sterile Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	First Generation Beta Lactam Antibiotics (Penicillin)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tanzo 4.5 g Injection by M/s Bosch, Reg. No. 039439
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 22-09-2020, wherein Dry powder injectable Penicillin section is declared.
	Name and address of API manufacturer.	M/s Shandong / (Previously Qilu Pharmaceuticals Co. Ltd) Anxin Pharmaceutical Co., Ltd. 849, Dongjia Town, Licheng District, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Tanzo 4.5 g Injection by M/s Bosch Pharma by performing quality tests (Identification, Assay and Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted

STABILITY STUDY DATA			
Manufacturer of API	M/s Shandong / (Previously Qilu Tianhe Pharmaceuticals Co. Ltd) Anxin Pharmaceutical Co., Ltd. 849, Dongjia Town, Licheng District, Jinan, Shandong, China		
API Lot No.	KA1007150016		
Description of Pack (Container closure system)	Glass Vial with rubber stopper sealed with flip off seal and packed in unit carton (1×1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	P5001	P5002	P5003
Batch Size	8,600 vials	8,600 vials	10,630 vials
Manufacturing Date	03-2015	03-2015	04-2015
Date of Initiation	16-04-2015	16-04-2015	04-06-2015
No. of Batches	03		

Documents submitted along with stability data.		
	Reference of previous approval of applications with stability study data of the firm (if any)	--
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2018001 issued by Shandong Food and Drug Administration valid till 24/07/2023.
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD DRAP I&E, Lahore dated 11-02-2015 for import of 100Kg of Piperacillin sodium: Tazobactam sodium (8:1)
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	N/A

Remarks of EvaluatorII:

Section#	**Observation**	**Firm's response**
3.2. S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer shall be submitted.	Submitted.

3.2.S.4.3	Analytical method verification studies from the drug product manufacturer shall be submitted.	Submitted.
3.2. S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.	Submitted.
3.2.P.2.2.1	Pharmaceutical equivalence studies against the innovator product shall be submitted.	Pharmaceutical equivalence has been submitted against the Tanzo Injection of M/s Bosch.
3.2.P.2.6	Compatibility studies with the reconstitution diluent shall be submitted.	Compatibility studies with water for injection have been submitted.
3.2.P.5.3	Test of specificity parameter has not been submitted in the analytical method verification studies.	Submitted.
3.2.P.8.3	Significant change i.e., more than 5% in the Assay results of Tazobactam has been reported in the accelerated stability studies data of batch# N5001 & N5002 of "2.25gm Injection." Firm has submitted following justification: We placed three consecutive batches of Talzon Sterile Dry Powder Injection 2.25g N500 I, N5002 and N5003 in 2015 from the respective supplier Shandlong, Pharmaceutical Co. Ltd. (Previously Qilu) for accelerated stability study at 40°C ± 2°C temperature and 75% ± 5% humidity and shelf life stability study at 30°C ± 2°C temperature and 65% ± 5%, humidity in which a slightly significant change was observed in N5001 and N5002 which might vary from analyst to analyst etc. Due to this significant change, we re-placed three consecutive batches of Talzon Sterile Dry Powder Injection 2.25g N900 I, N9002 and 1 9003 in 2019 from Shandong, Pharmaceutical Co. Ltd. (Previously Qilu) in which the results of the accelerated stability study and the shelf life stability are within limits and were found to be satisfactory. In addition, we are then placed one batch from the same supplier each year and-the results of all batches are within limits and deemed satisfactory. The details of new stability studies data submitted by firm for 2.25gm strength is as under:	

Description of Pack (Container closure system)	Glass Vial with rubber stopper sealed with flip off seal and packed in unit carton (1×1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	N9001	N9002	N9001
Batch Size	8,330 vials	8,330 vials	12,500 vials
Manufacturing Date	01-2019	04-2019	10-2019
Date of Initiation	23-01-2019	23-04-2019	08-11-2019

Documents submitted along with stability data.	
Reference of previous approval of applications with stability study data of the firm (if any)	--
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2018001 issued by Shandong Food and Drug Administration valid till 24/07/2023.

Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted for the relevant batch of API used for preparation of newly submitted drub product stability batches.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted for time duration of newly submitted stability batches.

- Firm has not submitted following for new stability studies data:
  i. Fee for revision of stability studies data.
  ii. COA of relevant batch of API used for preparation of newly submitted stability batches.
  iii. Complete batch manufacturing record.
  iv. Submitted stability studies record does not show performance of sterility testing.

Decision: Registration Board deferred the applications of Tazit 2.25gm Sterile Dry Powder for Injection & Tazit 4.5gm Sterile Dry Powder for Injection for submission of following:

i. Full fee of Rs. 75,000/- for revision of stability studies data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021
ii. COA of relevant batch of API used for preparation of newly submitted stability batches.
iii. Complete batch manufacturing record.
iv. Microbial reports for performance of sterility testing during stability studies.

283.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 31870 dated 19-11-2021
	Details of fee submitted	Rs.75,000/- dated 14-10-2021
	The proposed proprietary name / brand name	**Indaz IV 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: (Lyophilized powder for injection) Azithromycin Dihydrate Eq. to Azithromycin ……. 500mg
	Pharmaceutical form of applied drug	Intravenous Sterile Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use (macrolide)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Romycin Injection by M/s NabiQasim Industries.

	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 19-09-2020, wherein Small Volume Lyophilized injectables section is declared.
	Name and address of API manufacturer.	M/s Zhejiang Guobong Pharmaceutical Co., Ltd. No. 6, Weiwu Road, Hangzhou Gulf Shangyuu Economic and Technological Development Zone, Zheijnag, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the Zezot injection
	Analytical method validation/verification of product	Method verification studies have submitted

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Guobong Pharmaceutical Co., Ltd. No. 6, Weiwu Road, Hangzhou Gulf Shangyuu Economic and Technological Development Zone, Zheijnag, China.		
API Lot No.	103-200642-21		
Description of Pack (Container closure system)	Glass Vial with rubber stopper sealed with flip off seal and packed in unit carton (1×1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	394DS01	394DS02	394DS03
Batch Size	300 vials	300 vials	300 vials

Manufacturing Date	01-2021	01-2021	01-2021
No. of Batches	03		

Documents submitted along with stability data.

1.	Reference of previous approval of applications with stability study data of the firm (if any)	--
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20180112 issued by Shandong Food and Drug Administration valid till 04/09/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice GBPH2020 attested by AD DRAP I&E, Karachi dated 07-09-2020 for import of 100Kg of Azithromycin dihydrate (batch# 103-200642-21)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	N/A

Remarks of Evaluator[II]:

Firm had initially submitted trial batches data, while subsequently firm has submitted stability studies data of three commercial batches detailed as below:

Description of Pack (Container closure system)	Glass Vial with rubber stopper sealed with flip off seal and packed in unit carton (1×1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RYD001	RYD002	
Batch Size	20,300 vials	20,300 vials	
Manufacturing Date	04-2021	10-2021	
No. of Batches	03		

- Firm has not submitted following for new stability studies data:
  i. Fee for revision of stability studies data.
  ii. COA of relevant batch of API used for preparation of newly submitted stability batches.
  iii. Complete batch manufacturing record.
  iv. Details of drug substance used for the preparation of stability batches including evidence of procurement of Drug substance.
  v. Digital data logger record for stability chambers.

Decision: Deferred for submission of following:

i. Full fee of Rs. 75,000/- for revision of stability studies data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021
ii. COA of relevant batch of API used for preparation of newly submitted stability batches.
iii. Complete batch manufacturing record.
iv. Details of drug substance used for the preparation of stability batches including evidence of procurement of Drug substance.

Case no. 02 Registration applications of newly granted DML or New section (Human)

New DML

284.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.**
	Name, address of Manufacturing site.	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 4968 dated 22-02-2022
	Details of fee submitted	Rs.30,000/- dated 16-02-2022
	The proposed proprietary name / brand name	**Suliptin 50/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Sitagliptin Phosphate as Monohydrate Eq. to Sitagliptin …..… 50mg Metformin HCl ……..1000mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Manufacturer’s specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Sitamet Tablet of M/s CCL.
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 Tablet, Capsule, Dry powder and Ampoule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	**Sitagliptin phosphate monohydrate:** M/s Shangahi Rochi Pharmaceutical Co. Ltd. Pudong Shanghai, China. **Metformin HCl:** Active fine chemicals, Tejgaon , Dhaka.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Sitagliptin phosphate monohydrate:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, , specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP studie shave been performed against the Janumet tablet in three disollutin media of pH 1.2, pH 4.5 & pH 6.8 buffer.
	Analytical method validation/verification of product	Submitted for the specificity, precision and accuracy partameter.

STABILITY STUDY DATA

Manufacturer of API	**Sitagliptin phosphate monohydrate:** M/s Shangahi Rochi Pharmaceutical Co. Ltd. Pudong Shanghai, China. **Metformin HCl:** Active fine chemicals, Tejgaon , Dhaka.		
API Lot No.	**Sitagliptin phosphate monohydrate:** 20210615 **Metformin HCl:** MET012105018		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1/21	T2/21	T3/21
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	07-2021	07-2021	07-2021
No. of Batches	03		

285.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.**
	Name, address of Manufacturing site.	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 7361 dated 16-03-2022
	Details of fee submitted	Rs.30,000/- dated 11-03-2022
	The proposed proprietary name / brand name	**Suliptin 50/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Sitagliptin Phosphate as Monohydrate Eq. to Sitagliptin …..… 50mg Metformin HCl ……..500mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Sitamet Tablet of M/s CCL.
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 Tablet, Capsule, Dry powder and Ampule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	**Sitagliptin phosphate monohydrate:** M/s Shangahi Rochi Pharmaceutical Co. Ltd. Pudong Shanghai, China. **Metformin HCl:** Active fine chemicals, Tejgaon , Dhaka.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Sitagliptin phosphate monohydrate:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, , specifications, analytical procedure and its verification studies, batch analysis and justification

		of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP studie shave been performed against the Janumet tablet in three disollutin media of pH 1.2, pH 4.5 & pH 6.8 buffer.
	Analytical method validation/verification of product	Submitted for the specificity, precision and accuracy partameter.

STABILITY STUDY DATA			
Manufacturer of API	**Sitagliptin phosphate monohydrate:** M/s Shangahi Rochi Pharmaceutical Co. Ltd. Pudong Shanghai, China. **Metformin HCl:** Active fine chemicals, Tejgaon , Dhaka.		
API Lot No.	**Sitagliptin phosphate monohydrate:** 20210615 **Metformin HCl:** MET012105018		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T1/21	T2/21	T3/21
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	07-2021	07-2021	07-2021
No. of Batches	03		

Administrative Portion		
a	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sitagliptin phosphate monohydrate: Metformin HCl:
c	Documents for the procurement of API with approval from DRAP (in case of import).	Sitagliptin phosphate monohydrate: • Metformin HCl:
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.4.1	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required for both drug substances.	Submitted.
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method	Submitted.

	precision) performed by the Drug Product manufacturer shall be submitted for both drug substances.	
3.2.S.4.4	Submitted COAs of Sitagliptin from drug substance manufacturer and drug product manufacturer have different expiry dates.	Firm has declared it drafting error and has submitted rectified COA.
3.2.P.2.2.1	CDP report shall be submitted against the innovator product.	Firm has submitted CDP report against the Janumet tablet.
3.2.P.8.3	• Complete batch manufacturing record shall be submitted for all three stability batches. • Documents confirming procurement of drug substance shall be submitted. • Valid GMP certificates of drug substance manufacturer shall be submitted.	• Submitted. • Firm has submitted copy of License# 275, issued by DGDA Bangladesh for M/s Active fine chemicals, Dhaka, valid upto 04-10-2021. • Firm has submitted Goods declaration & DHL receipts for the import of both APIs

Decision: Registration Board approved the applications of Suliptin 50/500 mg Tablet & Suliptin 50/1000 mg Tablet with Innovator's specifications.

- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as for each strength, per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

286.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.**
	Name, address of Manufacturing site.	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 7361 dated 16-03-2022
	Details of fee submitted	Rs.30,000/- dated 11-03-2022
	The proposed proprietary name / brand name	**Caramox 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin as hydrochloride ……. 400mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Avelox tablet approved by US FDA
	For generic drugs (me-too status)	Avelox 400 mg Tablet by Bayer
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021

		Tablet, Capsule, Dry powder and Ampule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Saakh pharma Plot # C-7/1, North Western Industrial Zone Port Qasim , Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP studie shave been performed against the Moxifloxacin tablet of M/s Getz pharma in three disollutin media of pH 1.2, pH 4.5 & pH 6.8 buffer.
	Analytical method validation/verification of product	Submitted for the specificity, precision and accuracy partameter.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh pharma Plot # C-7/1, North Western Industrial Zone Port Qasim , Karachi.		
API Lot No.	21GN25-10006.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST20D023	ST20D024	ST20D025
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion		
a	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 83/2020-DRAP(K) issued by DRAP valid till 23/06/2023.
c	Documents for the procurement of API with approval from DRAP (in case of import).	• Local purchase from SAAKH PHARMA KARACHI.
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	N/A

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.4.1	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Submitted.
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Firm has submitted analytical method verification studies for drug substance.
3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	Submitted for batch# 21GN25-10006.
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies & CDP against the innovator product.	Firm has submitted that Phrmaceutical equivalence studies have been conducted by using Moxiget 400mg tablets of M/s Getz Pharma.
3.2.P.5.3	Accuracy parameter shall be performed on three sets of three concentration levels as recommended by ICH guidelines.	Firm has submitted analytical method verification studies including performance of accuracy parameter.
3.2.P.8.3	• Complete raw data sheet shall be submitted for the stability studies wherein details of sample and standard dilutions and calculation formula shall be submitted. • Complete batch manufacturing record shall be submitted for all three stability batches. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) • Documents confirming procurement of drug substance shall be submitted.	Firm has submitted commercial invoice no. MFX/2021/0001 from M/s Saakh Pharma for the procurement of 5Kg Moxifloxacin HCl. Complete batch manufacturing record for three stability batches have been submitted. Raw data sheets have been submitted.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration Board further decided that registration letter will be issued after submission of Pharmaceutical equivalence and CDP studies against the innovator product i.e., Avelox 400mg tablet.**		
287.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.**
	Name, address of Manufacturing site.	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8436 dated 31-03-2022
	Details of fee submitted	Rs.30,000/- dated 24-02-2022
	The proposed proprietary name / brand name	**Tamsulosin 0.4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Tamsulosin HCl Sustained Release Pellets Eq. To Tamsulosin HCl …… 0.4mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Alpha Blocker
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Flomax 0.4mg capsule by M/s ASTELLAS, Pharma. Inc Tokyo USFDA Approved.
	For generic drugs (me-too status)	Tamsolin 0.4 mg capsule by M/s GETZ Pharmaceuticals, Reg. No.
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 Tablet, Capsule, Dry powder and Ampule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical

		form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tamsolin 0.4mg capsule by GETZ Pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Tamsolin 0.4mg capsule by GETZ Pharmaceuticals in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Submitted for the specificity, precision and accuracy partameter.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Islamabad.		
API Lot No.	TMS317		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×07's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 capsules	2500 capsules	2500 capsules
Manufacturing Date	07-2021	07-2021	07-2021
No. of Batches	03		

Administrative Portion

a	Reference of previous approval of applications with stability study data of the firm (if any)	--
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F. 3-26/2019 issued by DRAP valid till 10/02/2022.

c	Documents for the procurement of API with approval from DRAP (in case of import).	• Local Purchase from M/s Vision Pharmaceuticals Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Islamabad,
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	N/A

Remarks of Evaluator^{II}:

Section#	Observations	Firm's response
3.2.S.4.1	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Submitted.
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Submitted.
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies & CDP against the innovator product.	Firm has submitted that Tamsolin 0.4mg capsule manufactured by Getz Pharma Pakistan Pvt. Ltd. was used due to unavailability of innovator packs.
3.2.P.5.3	Accuracy parameter shall be performed on three sets of three concentration levels as recommended by ICH guidelines.	Firm has submitted report for the performance of accuracy parameter.
3.2.P.8.3	• Complete batch manufacturing record shall be submitted for all three stability batches.	Batch manufacturing records for stability batches has been submitted.

Decision: Approved.

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

288.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Carer Pharmaceuticals plot No. 27 main RCCI road Rawat Industrial estate Islamabad Pakistan.**
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals plot No. 27 main RCCI road Rawat Industrial estate Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10054 dated 20-04-2022
	Details of fee submitted	Rs.30,000/- dated 29-03-2022
	The proposed proprietary name / brand name	**Iron Sucrose 100mg/5ml injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Elemental Iron (III) as Iron Sucrose …….100mg/5ml
	Pharmaceutical form of applied drug	Amber color Ampoule.
	Pharmacotherapeutic Group of (API)	(Anti-anaemic)
	Reference to Finished product specifications	BP
	Proposed Pack size	1×05's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Venofer 100mg/5ml by M/s RG Pharmaceutical, USFDA Approved.
	For generic drugs (me-too status)	Venofer 100 mg/5ml by M/s RG, Reg. No.
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 Tablet, Capsule, Dry powder and ampoules (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Chemiworld (Pvt.) Ltd. Plot No. 97-J Hayatabad Industrial estate Peshawar Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Venofer 100mg/5ml injection by RG Pharmaceuticals

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s CHEMIWORLD (Pvt.) Ltd Plot No. 97-J Hayatabad Industrial estate Peshawar Pakistan.		
API Lot No.	E19ISC128		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 ampoules	2500 ampoules	2500 ampoules
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	18-09-2021	18-09-2021	18-09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of letter of secretary CLB to M/s Chemiworld Pvt Lt. dated 18-02-2020 for grant of additional API i.e. Iron Sucrose Complex.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local Purchase from CHEMIWORLD (Pvt) Ltd Plot No. 97-J Hayatabad Industrial estate Peshawar Pakistan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Applied BP monograph states titration method fro Assay.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator[II]:

Decision: Approved.

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

M/s Enzon Pharma Labs Pvt Ltd. 5km Off Raiwind Manga Road, Lahore

CLB in its 273 meeting held on 15th January 2020 has considered and approved the grant of DML by way of Formulation. Now firm has applied for following products against each approved section

Section	**No of products applied**	**No of molecules applied**

Large Volume parenteral (IVP) General section	02	01
Small Volume parenteral (IVP) General section	01	01
Ampoule LDPE General	01	01

The firm applied following products previously which were considered in different meetings of RB as mentioned against each:

S.no	Brand Name	Generic Name	Composition	Meeting No and Registration status
1.	Ensol-NS 0.9% Infusion 500ml	Sodium Chloride	Each ml of the solution Contains: Sodium Chloride…9mg	M-307 Reg No: 110592
2.	Ensol-NS 0.9% Infusion 1000ml	Sodium Chloride	Each ml of the solution Contains: Sodium Chloride…9mg	M-307 Reg No: 110593
3.	Ensol-NS 0.9% Infusion 100ml	Sodium Chloride	Each ml of the solution Contains: Sodium Chloride…9mg	M-307 Reg No: 110591
4.	Ensol-NS 0.9% Infusion 25ml	Sodium Chloride	Each ml of the solution Contains: Sodium Chloride…9mg	M-307 Reg No: 109437
5.	Ensol-WFI 10ml	Water for Injection	Each 10ml Contains: Water for Injection…BP	M-307 Reg No: 109438
6.	Ensol-WFI 5ml	Water for Injection	Each 5ml Contains: Water for Injection…BP	M-307 Reg No: 109439
7.	Ensol-WFI 20ml	Water for Injection	Each 20ml Contains: Water for Injection…BP	M-307 Reg No: 109440
8.	Ensol-RL Compound Sodium Lactate IV Infusion 500ml	Sodium Chloride Potassium Chloride Calcium Chloride Dihydrate Sodium Lactate	Each 100ml Contains: Sodium Chloride…0.6% w/v Potassium Chloride…0.04% w/v Calcium Chloride Dihydrate…0.027% w/v Sodium Lactate…0.32% w/v	M-313 Reg No: 111623
9.	Ensol-RL Compound Sodium Lactate IV Infusion 1000ml	Sodium Chloride Potassium Chloride Calcium Chloride Dihydrate Sodium Lactate	Each 100ml Contains: Sodium Chloride…0.6% w/v Potassium Chloride…0.04% w/v Calcium Chloride Dihydrate…0.027% w/v Sodium Lactate…0.32% w/v	M-313 Reg No: 111624
10.	Ensol-Kcl 7.46% 20ml IV Injection	Potassium Chloride	Each ml contains: Potassium Chloride ..74.6mg	M-316 Registration letter under process
11.	Ensol-10% IV Infusion 1000ml	Glucose	Each 100ml Contains: Glucose Anhydrous…10gm	M-316 Reg No: 112895
12.	Ensol-5% IV Infusion 500ml	Glucose	Each 100ml Contains: Glucose Anhydrous…5gm	M-313 Reg No: 111628
13.	Ensol-5% IV Infusion 1000ml	Glucose	Each 100ml Contains: Glucose Anhydrous…5gm	M-313 Reg No: 111629
14.	Ensol-5% IV Infusion 100ml	Glucose	Each 100ml Contains: Glucose Anhydrous…5gm	M-313 Reg No: 111627

15.	Ensol-25% IV Injection 25ml	Glucose	Each ml Contains: Glucose Anhydrous…250mg	M-316 Reg No: 112896
16.	Ensol-10% IV Infusion 500ml	Glucose	Each 100ml Contains: Glucose Anhydrous…10gm	M-316 Reg No: 112894
17.	Ensol-25% IV Infusion 1000ml	Glucose	Each ml Contains: Glucose Anhydrous…250mg	Considered in M-320
18.	Ensol-Paed's IV Infusion 500ml	Glucose Anhydrous Sodium Chloride	Each 100ml Contains: Glucose Anhydrous…4.3g Sodium Chloride…0.18gm	M-316 Registration letter to be issued
19.	Ensol-DS 1000ml	Glucose Anhydrous Sodium Chloride	Each 100ml Contains: Glucose Anhydrous…5% w/v Sodium Chloride…0.9% w/v	M-313 Reg No: 111626
20.	Ensol-DS½ 500ml	Glucose Anhydrous Sodium Chloride	Each 100ml Contains: Glucose Anhydrous…5% w/v Sodium Chloride…0.45% w/v	M-316 Reg No: 112893
21.	Ensol-DS 500ml	Glucose Anhydrous Sodium Chloride	Each 100ml Contains: Glucose Anhydrous…5% w/v Sodium Chloride…0.9% w/v	M-313 Reg No: 111625
22.	Ensol-Metro 0.5% IV Infusion 100ml	Metronidazole	Each 100ml Contains: Metronidazole…0.5% w/v	Considered in M-320
23.	Ensol-RLD 500ml IV Infusion	Sodium Chloride Potassium Chloride Calcium Chloride Sodium Lactate Dextrose Anhydrous	Each 100ml Contains: Sodium Chloride…0.6% w/v Potassium Chloride…0.03% w/v Calcium Chloride**…**0.02% w/v Sodium Lactate…0.31% w/v Dextrose Anhydrous…5% w/v	To be considered in upcoming meeting
24.	Ensol-Cipro IV 0.2% Infusion	Ciprofloxacin	Each 100ml Contains: Ciprofloxacin as Ciprofloxacin Lactate…0.2% w/v	Considered in M-320

Summary of above molecules applied against each section is as below:

LVP GENERAL (above 100ml)	**SVP GENERAL (upto 100ml)**	**LDPE AMPOULE**
Sodium Chloride infusion	Sodium Chloride infusion	Water for Injection
Ringer Lactate infusion	Potassium Chloride injection	
Glucose infusion	Glucose infusion	
Glucose and sodium Chloride infusion	Metronidazole infusion	
Ringer Lactate and Dextrose infusion	Ciprofloxacin infusion	
Total molecules= 05	**Total molecules= 05**	**Total molecules = 01**

Now the firm has again applied 4 molecules (13 products) on 2nd August, 2022 with same formulation and same product development data but without **Eurocap packing.**

LVP GENERAL	**SVP GENERAL**	**LDPE AMPOULE**

(above 100ml)	**(upto 100ml)**	
Sodium Chloride infusion	Sodium Chloride infusion	
Ringer Lactate infusion	Glucose infusion	
Glucose infusion		
Glucose and sodium Chloride infusion		
Total molecules= 04	**Total molecules= 02**	**Total molecules = 00**

Now the firm has submitted following new applications of the same formulations previously approved with desired container closure system of without Euro cap, while referring to the product development data & stability studies data of previously submitted applications of same formulations approved by the Registration Board since the construction material of both packaging is same i.e., LDPE Bottles.

289.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21849 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Ensaline-NS 100ml 0.9% Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Sodium Chloride…0.9gm
	Pharmaceutical form of applied drug	Intravenous Infusion
	Pharmacotherapeutic Group of (API)	Other mineral supplements ATC CODE: (A12CA01)
	Reference to Finished product specifications	BP
	Proposed Pack size	100mL
	Proposed unit price	As per S.R.O.
	The status in reference regulatory authorities	Sodium Chloride 0.9% Intravenous Infusion BP of Baxter Healthcare Ltd. UK
	For generic drugs (me-too status)	Sterifluid-NS of M/S Frontier Dextrose Limited (Reg# 056330)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.

	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 307th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 307th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- NS 0.9% Infusion (100ml)
Dy. No. and date of submission	Dy. No. 12118: 22-04-2021
Batch No. of drug product	A, B, C
Case No.	91
Registration Board meeting	307th meeting of Registration Board held on 8th, 9th & 10th June 2021

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

290.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21850 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Ensaline-NS 500ml 0.9% Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Sodium Chloride…0.9gm
	Pharmaceutical form of applied drug	Intravenous Infusion
	Pharmacotherapeutic Group of (API)	Other mineral supplements ATC CODE: (A12CA01)
	Reference to Finished product	BP

	specifications	
	Proposed Pack size	500mL
	Proposed unit price	As per S.R.O.
	The status in reference regulatory authorities	Sodium Chloride 0.9% Intravenous Infusion BP of Baxter Healthcare Ltd. UK
	For generic drugs (me-too status)	Sterifluid-NS of M/S Frontier Dextrose Limited (Reg# 056330)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 307th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 307th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- NS 0.9% Infusion (500ml)
Dy. No. and date of submission	Dy. No. 12123: 22-04-2021
Batch No. of drug product	A, B, C
Case No.	92
Registration Board meeting	307th meeting of Registration Board held on 8th, 9th & 10th June 2021

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

291.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21851 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Ensaline-NS 1000ml 0.9% Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Sodium Chloride…0.9gm
	Pharmaceutical form of applied drug	Intravenous Infusion
	Pharmacotherapeutic Group of (API)	Other mineral supplements ATC CODE: (A12CA01)
	Reference to Finished product specifications	BP
	Proposed Pack size	1000mL
	Proposed unit price	As per S.R.O.
	The status in reference regulatory authorities	Sodium Chloride 0.9% Intravenous Infusion BP of Baxter Healthcare Ltd. UK
	For generic drugs (me-too status)	Sterifluid-NS of M/S Frontier Dextrose Limited (Reg# 056330)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 307th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 307th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- NS 0.9% Infusion (1000ml)
Dy. No. and date of submission	Dy. No. 12122: 22-04-2021
Batch No. of drug product	A, B, C
Case No.	93

	Registration Board meeting	307th meeting of Registration Board held on 8th, 9th & 10th June 2021

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

292.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 21848 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-5% 1000ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose Anhydrous…5gm
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Other IV Solution Additives ATC CODE: V06DC01
	Reference to Finished product specifications	BP
	Proposed Pack size	1000mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glucose 5% Intravenous Infusion BP of Baxter Healthcare Ltd. Caxton Way, Thetford Norfolk IP24 3SE United Kingdom
	For generic drugs (me-too status)	Sterifluid- 5 (Intravenous Infusion BP) of Frontier Dextrose Ltd. Plot No. 18/3, Phase- 1 Hatter Industrial Estate Haripur Pakistan (Reg # 049818)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.

	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- 5% IV Infusion 1000mL
Dy. No. and date of submission	Dy. No. 24871 dated 08/09/2021
Batch No. of drug product	A, B, C
Case No.	27
Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

293.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21845 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-5% 500ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose Anhydrous…5gm
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Other IV Solution Additives ATC CODE: V06DC01
	Reference to Finished product specifications	BP
	Proposed Pack size	500mL
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Glucose 5% Intravenous Infusion BP of Baxter Healthcare Ltd.Caxton Way, Thetford Norfolk IP24 3SE United Kingdom
	For generic drugs (me-too status)	Sterifluid- 5 (Intravenous Infusion BP) of Frontier Dextrose Ltd. Plot No. 18/3, Phase- 1 Hatter Industrial Estate Haripur Pakistan (Reg # 049818)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- 5% IV Infusion 500mL
Dy. No. and date of submission	Dy. No.24872 dated 08/09/2021
Batch No. of drug product	A, B, C
Case No.	26
Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

294.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21846 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-5% 100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose Anhydrous…5gm
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Other IV Solution Additives ATC CODE: V06DC01
	Reference to Finished product specifications	BP
	Proposed Pack size	100mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glucose 5% Intravenous Infusion BP of Baxter Healthcare Ltd.Caxton Way, Thetford Norfolk IP24 3SE United Kingdom
	For generic drugs (me-too status)	Macsol 5% (Intravenous Infusion BP) of SEARLE IV SOLUTIONS (PVT) LTD. 1.5 Km Manga Raiwind Road, Manga Mandi, Distt. Lahore - Pakistan (Reg # 069132)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- 5% IV Infusion 100mL
Dy. No. and date of submission	Dy. No.24872 dated 08/09/2021
Batch No. of drug product	A, B, C
Case No.	25
Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
295.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21845 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-10% 1000ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose Anhydrous …..… 10gm
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Other IV Solution Additives ATC CODE: V06DC01
	Reference to Finished product specifications	BP
	Proposed Pack size	1000mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glucose 10% Intravenous Infusion BP of Baxter Healthcare Ltd.Caxton Way, Thetford Norfolk IP24 3SE United Kingdom
	For generic drugs (me-too status)	Sterifluid- 10 (Intravenous Infusion BP) of Frontier Dextrose Ltd. Plot No. 18/3, Phase- 1 Hatter Industrial Estate Haripur Pakistan (Reg # 049819)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- 10% IV Infusion (1000mL)
Dy. No. and date of submission	Dy. No.24878 dated 08/09/2021
Batch No. of drug product	A, B, C
Case No.	29
Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

296.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21845 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-10% 500ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose Anhydrous …..… 10gm
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Glucose ATC CODE: V06DC01
	Reference to Finished product specifications	BP
	Proposed Pack size	500mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glucose 10% Intravenous Infusion BP of Baxter Healthcare Ltd.Caxton Way, Thetford Norfolk IP24 3SE

		United Kingdom
	For generic drugs (me-too status)	Sterifluid- 10 (Intravenous Infusion BP) of Frontier Dextrose Ltd. Plot No. 18/3, Phase- 1 Hatter Industrial Estate Haripur Pakistan (Reg # 049819)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- 10% IV Infusion (500mL)
Dy. No. and date of submission	Dy. No. 24877 dated 08/09/2021
Batch No. of drug product	A, B, C
Case No.	28
Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

297.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21840 dated 02-08-2022

	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-DS 500ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose Anhydrous …….. 5gm w/v Sodium Chloride ……. 0.9% w/v
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Other IV Solution Additives Glucose ATC CODE: V06DC01 Sodium Chloride ATC CODE: A12CA01
	Reference to Finished product specifications	BP
	Proposed Pack size	500mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Glucose DS Intravenous Infusion BP of **Baxter Healthcare Ltd.** Caxton Way, Thetford Norfolk IP24 3SE United Kingdom **BAXTER 0.9% SODIUM CHLORIDE and 5% GLUCOSE AHB1064 1000mL injection BP of TGA approved** https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-PI-01661-3&d=20211115172310101 Package size: 500 mL, 1000 mL 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL Any unused product or waste material should be disposed of in accordance with local requirements.
	For generic drugs (me-too status)	Sterifluid- DS (Intravenous Infusion BP) of Frontier Glucose Ltd. Plot No. 18/3, Phase- 1 Hatter Industrial Estate Haripur Pakistan (Reg # 050860)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	**Sodium Chloride:** Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China **Glucose Anhydrous:** Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- DS IV Infusion 500mL
Dy. No. and date of submission	Dy. No. 24873 dated 08/09/2021
Batch No. of drug product	A, B, C
Case No.	4
Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

298.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21841 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-DS 1000ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose Anhydrous …….. 5gm w/v Sodium Chloride ……. 0.9% w/v
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Other IV Solution Additives Glucose ATC CODE: V06DC01 Sodium Chloride ATC CODE: A12CA01
	Reference to Finished product specifications	BP
	Proposed Pack size	1000mL
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Glucose DS Intravenous Infusion BP of **Baxter Healthcare Ltd.**Caxton Way, Thetford Norfolk IP24 3SE United Kingdom BAXTER 0.9% SODIUM CHLORIDE and 5% GLUCOSE AHB1064 1000mL injection BP of TGA approved
	For generic drugs (me-too status)	Macsol- DS (Intravenous Infusion BP) of **SEARLE IV SOLUTIONS (PVT) LTD.** 1.5 Km Manga Raiwind Road, Manga Mandi, Distt. Lahore - Pakistan (Reg # 041433)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	**Sodium Chloride:** Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China **Glucose Anhydrous:** Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- DS IV Infusion 1000mL
Dy. No. and date of submission	Dy. No. 24874 dated 08/09/2021
Batch No. of drug product	A, B, C
Case No.	5
Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

299.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21842 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-RL 500ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Sodium Chloride…..…0.6% w/v Potassium Chloride……0.04% w/v Calcium Chloride Dihydrate…..…0.027% w/v Sodium Lactate……..0.32% w/v
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Sodium Chloride: Other mineral supplements ATC CODE: A12CA01 Potassium Chloride: Other mineral supplements ATC CODE: A12BA01 Calcium Chloride Dihydrate: Electrolyte replacement ATC CODE: A12AA07 Sodium Lactate: Alkalinizing Agents ATC CODE: A14AB08
	Reference to Finished product specifications	BP
	Proposed Pack size	500mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Compound Sodium Lactate Solution Intravenous Infusion BP of Baxter Healthcare Ltd. UK
	For generic drugs (me-too status)	Compound Sodium Lactate Infusion (Intravenous Infusion BP) of M/S Frontier Dextrose Ltd. (Reg # 052739)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Sodium Chloride: Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China Potassium Chloride: Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China Calcium Chloride Dihydrate: Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China Sodium Lactate: Luoyang Longmen Pharmaceutical Co., Ltd County Industrial Zone, Luoning, Henan, China.
	Module-II (Quality Overall	Firm has submitted QOS details as per WHO QOS PD

	Summary)	template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- RL Infusion (500ml)
Dy. No. and date of submission	Dy. No. 22585 dated 17/08/2021
Batch No. of drug product	A, B, C
Case No.	301
Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

300.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21843 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-RL 1000ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Sodium Chloride…..…0.6% w/v Potassium Chloride……0.04% w/v Calcium Chloride Dihydrate…..…0.027% w/v Sodium Lactate……..0.32% w/v
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of	Sodium Chloride:

	(API)	Other mineral supplements ATC CODE: A12CA01 Potassium Chloride: Other mineral supplements ATC CODE: A12BA01 Calcium Chloride Dihydrate: Electrolyte replacement ATC CODE: A12AA07 Sodium Lactate: Alkalinizing Agents ATC CODE: A14AB08
	Reference to Finished product specifications	BP
	Proposed Pack size	1000mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Compound Sodium Lactate Solution Intravenous Infusion BP of Baxter Healthcare Ltd. UK
	For generic drugs (me-too status)	Compound Sodium Lactate Infusion (Intravenous Infusion BP) of M/S Frontier Dextrose Ltd. (Reg # 052739)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	Sodium Chloride: Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China Potassium Chloride: Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China Calcium Chloride Dihydrate: Tianjin Haiguang Pharmaceutical Co., Ltd No.5 The seventh street TEDA, Tianjin, China Sodium Lactate: Luoyang Longmen Pharmaceutical Co., Ltd County Industrial Zone, Luoning, Henan, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 313th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 313th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- RL Infusion (1000ml)

	Dy. No. and date of submission	Dy. No. 22583 dated 17/08/2021
	Batch No. of drug product	A, B, C
	Case No.	302
	Registration Board meeting	313th meeting of Registration Board held on 16-18 Nov, 2021)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

301.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.**
	Name, address of Manufacturing site.	Enzon Pharma Labs Pvt Ltd 5km off Raiwind Manga Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 21839 dated 02-08-2022
	Details of fee submitted	Rs.30,000/- dated 25-07-2022
	The proposed proprietary name / brand name	**Enzol-DS½ 500ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose Anhydrous…..…5% w/v Sodium Chloride……..0.45% w/v
	Pharmaceutical form of applied drug	Intravenous Injection
	Pharmacotherapeutic Group of (API)	Other IV Solution Additives Glucose ATC CODE: V06DC01 Sodium Chloride ATC CODE: A12CA01
	Reference to Finished product specifications	BP
	Proposed Pack size	500mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	BAXTER 0.45% SODIUM CHLORIDE and 5% GLUCOSE AHB6028 1000mL injection BP of TGA approved
	For generic drugs (me-too status)	Sterifluid- DS ½ (Intravenous Infusion BP) of Frontier **Dextrose Ltd.** Plot No. 18/3, Phase- 1 Hatter Industrial Estate Haripur Pakistan (Reg # 342120)
	GMP status of the Finished product manufacturer	Last inspection conducted on 15 &16-10-2020 and report concludes that overall evaluation of inspection report rating is Good
	Name and address of API manufacturer.	**Sodium Chloride:** Nanchang Baiyun Pharmaceutical Co., Ltd Address: Yangzizhou Forest Farm, Qingshanhu District, Nanchang city, Jiangxi province, China **Glucose Anhydrous:**

		Weifang Shengtai Medicine Co., Ltd. The East of Changda Road, Changle county, Weifang Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Description of Pack (Container closure system)	LDPE bottle without Eurocap.

Remarks of Evaluator:

- The applied formulation to be manufactured by **M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore** has already been considered & granted approval by Registration Board in its 316th meeting with container closure system of "LDPE bottles with Eurocap" based on the data of same batches of drug product as submitted in the instant application. The details of the already considered product in 316th meeting are as follows:

Applicant firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Manufacturer firm	M/s Enzon Pharma Labs Pvt Ltd. 5km off Raiwind Manga Road, Lahore.
Brand Name	Ensol- RL Infusion (1000ml)
Dy. No. and date of submission	Dy. No. 24875 dated 08-09-2021
Batch No. of drug product	A, B, C
Case No.	199
Registration Board meeting	316th meeting of Registration Board held on 15-17 Mar, 2022)

Decision: Approved with container closure of "LDPE bottle without Eurocap."

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

Case no. 03 Registration applications for local manufacturing of (Human) drugs on Form 5

302.	**Name and address of manufacturer / Applicant**	**M/s. Star Laboratories Pvt Ltd Lahore**
	Brand Name +Dosage Form + Strength	Linista Met Tablets
	Composition	Each film coated Tablet Contains: Linagliptin …….2.5mg Metformin hydrochloride…..1000mg
	Diary No. Date of R& I & fee	Dy. No.2583; 20-06-2016; Rs.20,000/- (20-06-2016)
	Pharmacological Group	Antihyperglycemic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Not verifiable
	GMP status	Last inspection report dated 27-10-2016, recommended the grant of cGMP certificate for export purpose in respect of all sections
	Remarks of the Evaluator.	• No USP or BP monograph is available for applied formulation.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 274th meeting: Deferred in light of comments of IPO Pakistan.	
	Remarks of Evaluator:	
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
303.	**Name and address of manufacturer / Applicant**	**"M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad** Contract manufacturing by **M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Merolit 1gm Injection
	Composition	"Each vial contains: Meropenem……1gm"
	Diary No. Date of R& I & fee	Dy. No 16389 dated 07-03-2019 Rs50,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Mopen 1gm Injection of M/s Hilton Pharma
	GMP status	**Ipram:** Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[II]	Initially form has submitted stability study reports for accelerated conditions but now the applicant has requested a sunder: "This is our product Merolit 500mg & 1gm, its me too status is available, we want to withdraw its stability and require normal approval of product."
	Decision of 296th meeting: Deferred for consideration as per queue.	
	Evaluation by PEC: Application is now presented as per queue.	
	Decision: Approved. • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad wherein availability of atomic absorption spectrophotometer shall also be verified.**	
304.	**Name and address of manufacturer / Applicant**	**"M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad** Contract manufacturing by **M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad"**
	Brand Name + Dosage Form + Strength	Merolit 500mg Injection
	Composition	"Each vial contains: Meropenem…500mg"
	Diary No. Date of R& I & fee	Dy. No 16390 dated 07-03-2019 Rs50,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Mopen 500mg Injection of M/s Hilton Pharma
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.

	Remarks of the Evaluator [II]	
	Decision of 296th meeting: Deferred for consideration as per queue.	
	Evaluation by PEC: Application is now presented as per queue.	
	Decision: Approved. • **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad wherein availability of atomic absorption spectrophotometer shall also be verified.**	
305.	**Name and address of manufacturer / Applicant**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.**
	Brand Name + Dosage Form + Strength	Hyzinc oral solution
	Composition	"Each 5ml contains: Zinc sulphate monohydrate eq. to Elemental Zinc …… 10mg
	Diary No. Date of R& I & fee	R&I verified by Reg-II section vide letter no. F.1-11/2019-Reg-II dated 14-09-2022. Rs. 8,000/- Dated 10-08-2012, Rs. 409,000/- (Additional fee of 10 products) dated 12-03-2013
	Pharmacological Group	Mineral supplements
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Available in IP as solution (Available strengths: 10mg & 20mg of zinc per 5 mL)
	Me-too status (with strength and dosage form)	Zevro Syrup 10mg. Reg. No. 77058
	GMP status	The firm is granted GMP certificate based on inspection conducted on 09-06-2020.
	Evaluation by PEC:	
	Decision: Approved.	
306.	**Name and address of manufacturer / Applicant**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.**
	Brand Name + Dosage Form + Strength	Amophen syrup
	Composition	"Each 5ml contains: Ammonium chloride……100mg Chlorpheniramine maleate ……. 2mg Sodium citrate …… 58mg"
	Diary No. Date of R& I & fee	Dy. Dated 15-10-2012, R&I verified by Reg-II section vide letter no. F.1-11/2019-Reg-II dated 14-09-2022. Rs. 8,000/- Dated 10-08-2012, Rs. 409,000/- (Additional fee of 10 products) dated 12-03-2013
	Pharmacological Group	Expectorant/Antihistamine
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--
	GMP status	The firm is granted GMP certificate based on inspection conducted on 09-06-2020.
	Evaluation by PEC: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

	• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
307.	**Name and address of manufacturer / Applicant**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.**
	Brand Name + Dosage Form + Strength	Fanzibax suspension
	Composition	"Each 5ml contains: Sulfadoxine……500mg Pyrimethamine ……. 25mg
	Diary No. Date of R& I & fee	Dy. Dated 15-10-2012, R&I verified by Reg-II section vide letter no. F.1-11/2019-Reg-II dated 14-09-2022. Rs. 8,000/- Dated 10-08-2012, Rs. 409,000/- (Additional fee of 10 products) dated 12-03-2013
	Pharmacological Group	Sulfadoxine/Diaminopyrimidine
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--
	GMP status	The firm is granted GMP certificate based on inspection conducted on 09-06-2020.
	Evaluation by PEC: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
308.	**Name and address of manufacturer / Applicant**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.**
	Brand Name + Dosage Form + Strength	Latex oral solution
	Composition	"Each 5ml contains: Lactulose …… 3.35gm
	Diary No. Date of R& I & fee	Dy. Dated 15-10-2012, R&I verified by Reg-II section vide letter no. F.1-11/2019-Reg-II dated 14-09-2022. Rs. 15,000/- Dated 10-08-2012, Rs. 409,000/- (Additional fee of 10 products) dated 12-03-2013
	Pharmacological Group	Osmotic Laxative
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Duphalac (Lactulose 3.335 g/5 ml) clear, viscous liquid. MHRA approved
	Me-too status (with strength and dosage form)	Kohilac Syrup (Lactulose……3.35g). Reg. No. 55593
	GMP status	The firm is granted GMP certificate based on inspection conducted on 09-06-2020.
	Evaluation by PEC: • Firm has submitted documents from the source of Lactulose from M/s Lacsa (Pty) Ltd, 72 Ballantrae Road, Merebank, Durban, 4052, Kwa-Zulu Natal, South Africa including COA stability studies data and GMP certificate no. API26/7/3/3/1/G0036/2022 issued by South African Health Products Regulator Authority valid upto 09-06-2023. Firm has also submitted MHRA GMP certificate no. UK API 14420 Insp GMP 14420/5065-0008 issued on basis of inspection conducted on 20-08-2019.	

	Decision: Approved.	
309.	**Name and address of manufacturer / Applicant**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.**
	Brand Name + Dosage Form + Strength	Acymax syrup
	Composition	"Each 5ml contains: Acefylline piperazine …… 125mg
	Diary No. Date of R& I & fee	R&I verified by Reg-II section vide letter no. F.1-11/2019-Reg-II dated 14-09-2022. Rs. 8,000/- Dated 10-08-2012
	Pharmacological Group	Xanthines
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Acefyl syrup by Nabiqasim
	GMP status	The firm is granted GMP certificate based on inspection conducted on 09-06-2020.
	Evaluation by PEC: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
310.	**Name and address of manufacturer / Applicant**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.**
	Brand Name + Dosage Form + Strength	Hepamax syrup
	Composition	Each ml contains:- Ornithine Aspartate……60mg Nicotinamide…….4.8mg Riboflavin …... 5mg Phosphate sodium…….0.153mg
	Diary No. Date of R& I & fee	R&I verified by Reg-II section vide letter no. F.1-11/2019-Reg-II dated 14-09-2022. Rs. 8,000/- Dated 10-08-2012
	Pharmacological Group	Supportive therapy for liver disease.
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	--
	GMP status	The firm is granted GMP certificate based on inspection conducted on 09-06-2020.
	Evaluation by PEC: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
311.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi.**
	Brand Name + Dosage Form + Strength	Fidaxo 60mg Tablet

	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…..…60mg
	Diary No. Date of R& I & fee	R&I Dy.No 3974 dated 31-01-2018 verified by R&I Incharge, Rs.20,000 dated 31-01-2018.
	Pharmacological Group	Antihistamine for systemic use.
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Vigil Tablets, Tabros Pharma, Reg. No. 39776
	GMP status	GMP certificate issued on 06-10-2020 on the basis on inspection conducted on 07-08-2019.
	Evaluation by PEC:	
	Decision: Approved.	
312.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Noriday 5mg Tablet
	Composition	Each Tablet Contains: Norethisterone Acetate ……. 5mg
	Diary No. Date of R& I & fee	R&I Dy.No 41482 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Progestogen
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHR of UK
	Me-too status (with strength and dosage form)	Postpon-M Tablet by M/s OBS, (Reg# 073532)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
313.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Tibogen 2.5mg Tablet
	Composition	Each Tablet Contains: Tibolone…….2.5mg
	Diary No. Date of R& I & fee	R&I Dy.No 41484 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Estrogens
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Livial 2.5 mg tablets of MHRA approved
	Me-too status (with strength and dosage form)	Tibopause Tablets 2.5mg by M/s Zafa Pharmaceuticals (Reg# 024213)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.

	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
314.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Mestif 25mg Tablet
	Composition	Each Tablet Contains: Mesterolone…….25mg
	Diary No. Date of R& I & fee	R&I Dy.No 41485 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Androgen (5-androstanon (3) derivative)
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pro-viron of MHRA approved
	Me-too status (with strength and dosage form)	Androviron 25mg Tablets by M/s Global (Reg# 030471)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
315.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Lynest 500mcg Tablet
	Composition	Each Tablet Contains: Lynestrenol ……500mcg
	Diary No. Date of R& I & fee	R&I Dy.No 41487 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Androgen (5-androstanon (3) derivative)
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pro-viron of MHRA approved
	Me-too status (with strength and dosage form)	Androviron 25mg Tablets by M/s Global (Reg# 030471)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
316.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	C-Ethin 2mg/35mcg Tablet
	Composition	Each Film Coated Tablet Contains: Cyproterone as Acetate…2mg Ethinyloestradiol……..35mcg

	Diary No. Date of R& I & fee	R&I Dy.No 41486 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dermapil film coated tablet, TGA Approved.
	Me-too status (with strength and dosage form)	DIANE-35 by Bayer Health care (Reg. No. 011467), Eva-35 tablet by M/s Hansel (Reg#064796)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
317.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	C-Ethin 2mg/35mcg Tablet
	Composition	Each Film Coated Tablet Contains: Cyproterone as Acetate…2mg Ethinyloestradiol……..35mcg
	Diary No. Date of R& I & fee	R&I Dy.No 41486 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dermapil film coated tablet, TGA Approved.
	Me-too status (with strength and dosage form)	DIANE-35 by Bayer Health care (Reg. No. 011467), Eva-35 tablet by M/s Hansel (Reg#064796)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
318.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Lynest 500mcg Tablet
	Composition	Each Tablet Contains: Lynestrenol ……. 500mcg
	Diary No. Date of R& I & fee	R&I Dy.No 41487 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Progestogen
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exluton, 0.5 mg tablet by M/s N.V. Organon (Netherland approved)
	Me-too status (with strength and dosage form)	Minipyl 500mcg Table by M/s Zafa Pharmaceuticals (Reg# 081463)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.

	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
319.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Etges 0.02mg/0.075mg tablet
	Composition	Each Film Coated Tablet Contains: Ethiynlestradiol ……. 0.2mg Gestodene ……. 0.075mg
	Diary No. Date of R& I & fee	R&I Dy.No 41483 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Hormonal contraceptives for systemic use (Progestogens and estrogens, fixed Combinations)
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aidulan 20/75 microgram film-coated tablets of MHRA approved
	Me-too status (with strength and dosage form)	Meliane Tablets of M/s Medipharm Reg# 024076
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
320.	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Citro-Mon sachet
	Composition	Each sachet Contains: Citric acid ……. 0.702gm Sodium citrate …... 0.613gm Tartaric acid …… 0.858gm Sodium bicarbonate …… 1.716gm
	Diary No. Date of R& I & fee	R&I Dy.No 1614 dated 17-10-2016 verified by R&I Incharge, Rs.20,000/- dated 17-10-2016
	Pharmacological Group	Gastric antacid and urinary alkalising agent
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--
	GMP status	Inspection report dated 11-12-2019 wherein the firm is operating at an acceptable level of GMP.
	Evaluation by PEC: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	

Case no. 04 Registration applications of Form 5 with stability studies data.

321.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hudson Pharma Pvt. Ltd Karachi**
	Brand Name +Dosage Form + Strength	Dexireg 30mg capsule
	Composition	Each Delayed Release capsule contains:- Dexlansoprazole (as enteric coated pellets) ….. 30mg
	Diary No. Date of R& I & fee	Dy.No 979 dated 26-11-2015 Rs.50,000/- Rs. 50,000/- dated 14-05-2020 vide deposit slip# 1984376
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	Rs.1330 /14's Rs.2660/28's
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 16th-28th Aug, 2018 concludes as under: "The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance."
	Remarks of the Evaluator[II]	
1.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hudson Pharma Pvt. Ltd Karachi**
	Brand Name +Dosage Form + Strength	Dexireg 60mg capsule
	Composition	Each Delayed Release capsule contains:- Dexlansoprazole (as enteric coated pellets) ….. 60mg
	Diary No. Date of R& I & fee	Dy. No 997 dated 26-11-2015 Rs.50,000/- Rs. 50,000/- dated 14-05-2020 vide deposit slip# 1984373
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	Rs.2100 /14's Rs.4200/28's
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 16th-28th Aug, 2018 concludes as under: "The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance."
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA	
Drug	Dexireg capsules
Name of Manufacturer	M/s Barret Hodgson, Karachi
Manufacturer of API	M/s Murli Krishna Pharma Pvt. Ltd., Maharashtra, India
API Lot No.	MKPPLR-DLF-18022
Description of Pack	Alu-Alu blister

(Container closure system)		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH	
Time Period	Accelerated: 6 months Real Time: 6 months	
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6 (Months)	
Product	Dexireg 30	Dexireg 60
Batch#	EXP-C-157,PLT-C-021,PLT-C-022	EXP-C-158,PLT-C-024,PLT-C-023
Batch Size (No. of capsules)	500,1000,1000	500,1000,1000
Manufacturing Date	11-10-2018,08-11-2018,08-11-2018	110-2018, 11-2018, 08-11-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	• Copy of COA from M/s Murli Krishna Pharma Pvt. Ltd., Maharashtra, India has been submitted.
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (NEW-WHO-GMP/CERT/PD/80503/2019/11/27529) for the M/s Murli Krishna Pharma Pvt. Ltd., Maharashtra, India, issued valid upto 03-04-2022.
Protocols followed for conduction of stability study and details of tests.	+Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Form 6 issued by the AD I&E DRAP Karachi dated 12-10-2018 has been submitted for the procurement of 5gm Dexlansoprazole DDR pellets 23% from M/s Murli Krishna Pharma Pvt. Ltd., Maharashtra, India.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The submitted Import license mentions procurement of 5gm of Dexlansoprazole 23% pellets. Justify the manufacturing of 3 batches each of Dexireg 30mg & Dexireg 60mg capsules with this imported quantity of pellets.
- **Firm's response:**
  "We would like to inform you that we procured API i.e., Dexlansoprazole (23% pellets) in quantity of 1.2 Kg for manufacturing of stability batches on 08-06-2018 for which we have by mistake, missed to apply for DIL/form-6. However, we later procured further Dexlansoprazole (23% pellets) on 17-07-2018 with its proper DIL/Form 6 on 12-10-2018.
  We further undertake that we will in future comply all the requirements as laid down in given DRAP's procedure/SOP."

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Dexireg (Dexlansoprazole) 30mg and Dexireg (Dexlansoprazole) 60mg Capsules by M/s Barrett Hudson Pharma, Pvt. Ltd, Karachi.

Reference No: F.1-2/2020-PEC dated 03rh November, 2020.
Investigation Date and Time: 01st September, 2022.
Investigation Site: Factory premises of M/S. Barrett Hudson Pharma Pvt. Ltd., Karachi.
Background:

Chairman Registration Board considered the applications of M/S. Barrett Hudson Pharma Pvt. Ltd., Karachi for registration of Dexireg (Dexlansoprazole) 30mg & Dexireg (Dexlansoprazole) 60mg Capsules and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

1. Prof. Dr. Rafeeq Alam Khan, Dean. Faculty of Pharmacy, Ziauddin University, Karachi (Member Registration Board).
2. Dr. Saif-ur-Rehman Khattak, Director/ FGA, CDL, Karachi.
3. Mr. Kirshan Das, Assistant Director, DRAP Office Karachi (Who could not joined the inspection due to his transfer to Quetta, Baluchistan).

Sr. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API?	The firm has imported 1.2 Kg (23% w/w, batch No. MKPPLR-DLF-18022) Dexlansoprazole dual delayed release pellets from M/S. Murli Krishna Pharma (Pvt.) Ltd., India on 08-06-2018 and used in stability batches of 30 mg and 60mg Dexireg Capsules.
2.	What was the rationale behind selecting the particular manufacturer of API?	An SOP for induction and approval of new vendors is in place and implemented. The SOP include requirement like GMP certificate, capability of providing reference standards, proper QMS etc.
3.	Do you have documents confirming the import of API reference standard and impurity standards?	The firm has documents confirming the import of reference standard of API & two impurities (Sulphone & Sulfide).
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificate of analysis of the API, working standard of the API and impurity standards.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate issued by the concerned government.
6.	Do you use API manufacturer method of testing?	The firm has used the API manufacturer method for testing of the API after proper validation.
7.	Do you have stability studies reports on API?	The firm has stability study (accelerated and real time) reports on the three batches of the API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability studies have been performed as per stability indicating method and major degradation products (sulphide and sulphone) have been quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of the API, reference standards of the API and impurities (Sulphone and Sulphide).
11.	Have you used pharmaceutical grade excipients?	Not applicable, as no excipient is added before encapsulation i.e., the API is received as dual delayed release pellets and are filled in capsule shells as such.

<table>
<tr><td></td><td></td><td>However the capsules shells used were of pharmaceutical grade.</td></tr>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>Local gelatine shells have been used by the firm for which there are proper documents of purchase available with the firm.</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>Test reports and other documents are available for empty gelatine capsules.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of API tablets / capsules?</td><td>The firm has written and authorized protocol for development of Dexireg 30mg / 60mg capsules.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipient compatibility studies?</td><td>Not applicable, as no excipients are added before encapsulation.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The firm has performed comparative dissolution studies on their capsules with Razodex (Getz Pharma) Capsules. The results of dissolution are comparable. Since there is only use of gelatine capsules in addition to the pellets whose effect on dissolution is negligible, therefore, the study can be warranted as ok, however, it is advised that for other products innovator brands should be used.</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section?</td><td>The firm has product development (R&D) section with requisite manufacturing and testing facilities.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of Dexlansoprazole Capsules?</td><td>All the necessary equipment are available in product development section however, the encapsulation is done in production area using qualified encapsulation machine.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The equipment in product development section (R&D) are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>PD equipment are included in site equipment maintenance, calibration and qualification program.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has adequately qualified and trained staff in product development section.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of capsules as required?</td><td>The firm has manufactured three stability batches each for 30mg and 60mg capsules.
<table>
<tr><th colspan="3">Dexireg 30mg capsules</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg</th><th>Batch Size</th></tr>
<tr><td>EXP-C-157</td><td>11-10-2018</td><td>500 capsules</td></tr>
<tr><td>PLT-C-021</td><td>08-11-2018</td><td>1000 capsules</td></tr>
<tr><td>PLT-C-022</td><td>08-11-2018</td><td>1000 capsules</td></tr>
<tr><th colspan="3">Dexireg 60mg capsules</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg</th><th>Batch Size</th></tr>
<tr><td>EXP-C-158</td><td>12-10-2018</td><td>500 capsules</td></tr>
<tr><td>PLT-C-023</td><td>09-11-2018</td><td>1000 capsules</td></tr>
<tr><td>PLT-C-024</td><td>09-11-2018</td><td>1000 capsules</td></tr>
</table></td></tr>
<tr><td>23.</td><td>What was the criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches was the number of capsules used per test and frequency of testing along with smooth operation on the capsule filling machine.</td></tr>
</table>

24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has validated HPLC methods provided by manufacturer of the API with the necessary force depredation studies.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Full validation studies are performed.
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of product's API and the finished drug?	The firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of Dexlansoprazole API and the finished product.
29.	Do your method of analysis stability indicating?	Analytical method used in stability studies is stability indicating as evidenced by force degradation studies.
30.	Do your HPLC software is 21CFR compliant?	HPLC software is 21CFR compliant.
31.	Can you show Audit Trail reports on API testing?	Audit Trail reports of API (Dexlansoprazole pellets) and Dexireg Capsules are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches and the degradation products.
33.	Do you have commitment batches kept on stability testing?	The firm has completed accelerated (six months) and real time (24 months) studies on their stability batches with satisfactory results.
34.	Do you have valid calibration status for the equipment used in API tablets production in analysis?	The firm has valid calibration status for the equipment used in production and analysis of Dexlansoprazole Capsules**.**
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has adequate monitoring and control available for stability chambers.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are GMP compliant
37.	**<u>Specific Queries by PEC/Board</u>** Verify the record of purchase of 1.2 Kg of Dexlansoprazole (23% pellets), from relevant log book?	The record of purchase of Dexlansoprazole (23% pellets) was verified from the relevant record book.

Conclusions:

3. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Dexireg 30mg and Dexireg 60mg (Dexlansoprazole) Capsules are verifiable to satisfactory level.

4. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Dexireg 30mg and Dexireg 60mg (Dexlansoprazole) Capsules.

Decision: Registration Board approved the applications of o Dexireg 30mg capsule & Dexireg 60mg capsule with Innovator's specifications.

- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications of each strength as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 05 Registration applications of Import (Human) drugs

322.	Name, address of Applicant / Importer	M/s Ahsan Pharma, room No. 2, Delhi Muslim Building, Aram Bagh road Karachi.
	Details of Drug Sale License of importer	License No: 048 Address: Ahsan Pharma Room No. 2, Dehli Muslim Buidling Aram Bagh road Karachi. Godown: B-4, SITE Katachi. Validity: 15/10/2022 Status: Drug License by the way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Limited, Bedford Bussiness Centre, 61-63 St.Peter's Street, Bedford, MK40 2PR, United Kingdom.
	Name, address of manufacturer(s)	Manufacturer: M/s Sichuan Huiyu Pharmaceutical Company Limited, Building 3, No. 333 Hanyang road, Shizhong District Neijang, Sichuan, CN-641000, China. Batch releasing site: M/s Seacross Pharmacueticals Limited, Stanmore Place, Howard road, Stanmore, HA7 1BT, United Kingdom.
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate) • Copy of GMP certificate (No. SC20180007) issued by CFDA valid till 27/05/2023 for manufacturer. • Copy of CoPP (certificate No.PP10169762) issued by MHRA on 12/01/2021. The applied product is present in the market of exporting country. **Note:** The CoPP does not specifies the filled volume but it describes the strength that is 5mg/ml. One single Copp is submitted for both filled volumes. The SmPc is attached with copy of CoPP which mentions both the filled volumes, 10ml as well as 20ml.	
	Details of letter of authorization / sole agency agreement • Copy of exclusive distribution ship agreement is submitted by the firm signed by the manufacturer, product license holder (abroad) and the applicant whereby M/s Ahsan Pharma is given an exclusive right to register, market and sell different product including the applied product.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 7316 : 05-03-2021
	Details of fee submitted	PKR 100,000/- : 22-02-2021

	The proposed proprietary name / brand name	Oxaliplatin 5mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Oxaliplatin……..5mg
	Pharmaceutical form of applied drug	Concentrate for solution for infusion
	Pharmacotherapeutic Group of (API)	Antineoplastic
	Reference to Finished product specifications	USP
	Proposed Pack size	20ml vial per box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Eloxatin 100mg/20ml vial by M/s Sanofi, USFDA Approved.
	For generic drugs (me-too status)	Eloxatin 100mg/20ml by M/s Sanofi, Reg. No. 44891
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Umicore Argentina S.A. 14 street, Building #229, Argentina-B1629 MXA Pilar Industrial Park, Buenos Aires Province, Argentina.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation analytical procedures and validation for impurities, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The firm has submitted copy of certificate of suitability No. R1-CEP 2010-002-Rev 01 and has not submitted the stability data of drug substance. However, the firm has stated that the re-test period for drug substance is 48 hours.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is established against Eloxatin, concentrate for solution for infusion

		approved in Greece by performing all the quality tests.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Clear type I glass vial (20ml) with Teflon-coated chlorobutyl rubber stoppers and aluminium caps.
	Stability study data of drug product, shelf life and storage conditions	• Real time stability studies have been conducted at 25°C±2 and 60%RH±5% for 24 months of 3 batches • Accelerated stability study is conducted at 40oC±2 and 75%RH±5% for 6 months of 3 batches Batches: 2321808012, 2321809012, 2321809022
323.	**Name, address of Applicant / Importer**	**M/s Ahsan Pharma, room No. 2, Delhi Muslim Building, Aram Bagh road Karachi.**
	Details of Drug Sale License of importer	License No: 048 Address: Ahsan Pharma Room No. 2, Dehli Muslim Buidling Aram Bagh road Karachi. Godown: B-4, SITE Katachi. Validity: 15/10/2022 Status: Drug License by the way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Limited, Bedford Bussiness Centre, 61-63 St.Peter's Street, Bedford, MK40 2PR, United Kingdom.
	Name, address of manufacturer(s)	Manufacturer: M/s Sichuan Huiyu Pharmaceutical Company Limited, Building 3, No. 333 Hanyang road, Shizhong District Neijang, Sichuan, CN-641000, China. Batch releasing site: M/s Seacross Pharmacueticals Limited, Stanmore Place, Howard road, Stanmore, HA7 1BT, United Kingdom.
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate) • Copy of GMP certificate (No. SC20180007) issued by CFDA valid till 27/05/2023 for manufacturer. • Copy of CoPP (certificate No.PP10169762) issued by MHRA on 12/01/2021. The applied product is present in the market of exporting country. **Note:** The CoPP does not specifies the filled volume but it describes the strength that is 5mg/ml. One single Copp is submitted for both filled volumes. The SmPc is attached with copy of CoPP which mentions both the filled volumes, 10ml as well as 20ml.	
	Details of letter of authorization / sole agency agreement • Copy of exclusive distribution ship agreement is submitted by the firm signed by the manufacturer, product license holder (abroad) and the applicant whereby M/s Ahsan Pharma is given an exclusive right to register, market and sell different product including the applied product.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 7318 : 05-03-2021
	Details of fee submitted	PKR 100,000/- : 22-02-2021
	The proposed proprietary name / brand name	Oxaliplatin 5mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Oxaliplatin……..5mg
	Pharmaceutical form of applied drug	Concentrate for solution for infusion
	Pharmacotherapeutic Group of (API)	Antineoplastic
	Reference to Finished product specifications	USP
	Proposed Pack size	10ml vial per box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Eloxatin 50mg/10ml vial by M/s Sanofi, USFDA Approved.
	For generic drugs (me-too status)	Eloxatin 50mg/10ml by M/s Sanofi, Reg. No. 44890
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Umicore Argentina S.A. 14 street, Building #229, Argentina-B1629 MXA Pilar Industrial Park, Buenos Aires Province, Argentina.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation analytical procedures and validation for impurities, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The firm has submitted copy of certificate of suitability No. R1-CEP 2010-002-Rev 01 and has not submitted the stability data of drug substance. However, the firm has stated that the re-test period for drug substance is 48 hours.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing

		process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is established against Eloxatin, concentrate for solution for infusion approved in Greece by performing all the quality tests.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Clear type I glass vial (10ml) with Teflon-coated chlorobutyl rubber stoppers and aluminium caps.
	Stability study data of drug product, shelf life and storage conditions	• Real time stability studies have been conducted at 25ºC±2 and 60%RH±5% for 24 months of 3 batches • Accelerated stability study is conducted at 40oC±2 and 75%RH±5% for 6 months of 3 batches Batches: 2311808012, 2311808022, 2311808032

Evaluation by PEC:

Observations	Response by the firm
Analytical method verification studies including specificity, accuracy and precision for drug substance are required and relevant information should be presented in section 2.3.S.5 and 3.2.S.5 under control of Drug Substance.	Submitted from M/s Sichuan Huiyu Pharmaceutical Company Limited, Building 3, No. 333 Hanyang road, Shizhong District Neijang, Sichuan, CN-641000, China.
Pharmaceutical equivalence studies are not provided with the relevant details. Provide the required data of pharmaceutical equivalence along with details of manufacturer, approval status in reference countries, batch number, date of manufacturing and expiry date of the reference product against which the pharmaceutical equivalence has been established.	Firm has submitted following details of reference product against which Pharmaceutical equivalence has been performed. Innovator: Eloxatin® Manufacturer: Sanofi Aventis Approval status: Approved in the European community since 1996 Batch number: D8A696 Expiry data: 01/2011
Real time stability studies of the drug product are performed at 25ºC±2 and 60%RH±5% while the said study should be performed according to zone IV-A conditions that is 30ºC±2 and 65%RH±5% of 03 batches till claimed shelf life.	Firm has submitted new stability studies data of three batches of both filled volumes as below: • Real time stability studies have been conducted at 30ºC±2 and 65%RH±5% for 24 months of 3 batches • Accelerated stability study is conducted at 40ºC±2 and 75%RH±5% for 6 months of 3 batches Fee for revision of stability studies data shall be submitted.

Decision: Registration Board approved applications of Oxaliplatin 5mg/ml concentrate for solution for infusion (20ml) & Oxaliplatin 5mg/ml concentrate for solution for infusion (10ml) as per policy of inspections of manufacturer abroad.

324. Neuair Discair Fluticasone Propionate 100mcg & Salmeterol (Eq. to Salmeterol xinafoate) 50mcg Inhalational powder by M/s The Searle company Limited Karachi

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 12000 Dated 16-07-2019 (Rs. 100,000/- Dated 12-07-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s The Searle company Limited, 1st floor N.I.C.L Building Abbasi Shaheed Road off: Shahrah-E-Faisal Karachi-75530
	1.3.2	Name, address and contact details of Manufacturing site. M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey
	1.3.3	Specify whether the Applicant is: Importer
	1.3.4	Drug Sale License M/s The Searle company Limited, suit no. 101 1st floor N.I.C Building Abbasi Shaheed Road Karachi Godowns address: F-2/Q SITE Karachi Drug License by way of Wholesale No. 0591 valid upto 03-05-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale
	1.4.2	For imported products, please specify one of following: □ Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Salmeterol / Fluticasone Propionate
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each dose contains: Fluticasone Propionate 100mcg & Salmeterol (Eq. to Salmeterol xinafoate) 50mcg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Neuair Discair
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's (60 Doses)
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Bronchodilator+ Corticosteroids
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Oral Inhalation
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Not provided
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Seretide Accuhaler 50 microgram/100 microgram/ dose inhalation powder, pre-dispensed.
	1.5.10	Dosage form of applied drug

		Oral Inhalation
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. Submitted
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. Submitted
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Salmeterol API Manufacturer: Inke, S.A. Address: C/ Argent, 1 Area Industrial Del Llobregat Spain-08755 Castellbisbal, Barcelona. Fluticasone Propionate API Manufacturer: M/s Sterling S.P.A, Via Della Carboneria 30 Italy- 06073 Solomeo Di Corciano, Perudia
	Original Legalized CoPP (Certificate#. 2018/3232) issued on 18-09-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency and applied product is not in free sale in exporting country but GMP status of manufacturer i.e., M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey is compliant. valid until 18/09/2020. Original Notarized "Product specific Letter of Authorization" from M/s Neutec Inhaler Ilac San. Ve Tic. A.S,, Turkey declaring M/s The Searle company Limited authorized for registration approval. Dated 16.10.2018 Authorization valid for three years.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

Firm Submitted CEP (Certification of suitability of European Pharmacopoeia monographs) for Salmeterol API which is verified by EDQM website dated 11-12-2019 link attached:
https://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP?vSelectName=1&Case_TSE=none&vContains=1&vContainsDate=1&vtsubName=Salmeterol&vtsubDateBegin=&vtsubDateBtwBegin=&vtsubDateBtwEnd=&SWTP=1&OK=Search
Firm Submitted CEP (Certification of suitability of European Pharmacopoeia monographs) for Fluticasone propionate API which is verified by EDQM website dated 11-12-2019 link attached:
https://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP?vSelectName=1&Case_TSE=none&vContains=1&vContainsDate=1&vtsubName=fluticasone&vtsubDateBegin=&vtsubDateBtwBegin=&vtsubDateBtwEnd=&SWTP=1&OK=Search

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted

	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data of 24 months (time points 0,6,9,12 & 24 Months) at 300C±65%RH and 6 months at 400C±75%RH for three batches.

Remarks of evaluator:
Firm has submitted three batches long term stability data of 24 months (time points 0,6,9,12 & 24 Months) at 300C±65%RH and 6 months at 400C±75%RH for three batches.
Original Legalized COPP issued by concern regulatory body of exporting country show that applied product is not in free sale in exporting country.
Decision of 293rd meeting: Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP.

Firm's response: Firm has submitted Original Legalized COPP (Certificate no. 2022/51) valid till 06-01-2024, issued by Ministry of Health, Turkish Medicines and medical Devices Agency, for Neuair Discair 50/100mcg Inhalation Powder declaring following details:

Product License Holder: M/s Neutec Ilac, San. Tic. A.S. , Yildiz Teknik Universitesi Davutpasa Kampusu Teknoloji gelistirme Bolgesi D1 Blok kat: 3 Esenler/Istanbul/Turkey

Manufacturer: M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey

Free Sale status: Available in country of origin i.e., Turkey.
GMP status of Manufacturer: Yes

Decision: Approved as per policy of inspections of manufacturer abroad.

325. Neuair Discair Fluticasone Propionate 250mcg & Salmeterol (Eq. to Salmeterol xinafoate) 50mcg Inhalational powder by M/s The Searle company Limited Karachi

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 12002 Dated 16-07-2019 (Rs. 100,000/- Dated 12-07-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s The Searle company Limited, 1st floor N.I.C.L Building Abbasi Shaheed Road off: Shahrah-E-Faisal Karachi-75530
	1.3.2	Name, address and contact details of Manufacturing site. M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	Drug Sale License M/s The Searle company Limited, suit no. 101 1st floor N.I.C Building Abbasi Shaheed Road Karachi Godowns address: F-2/Q SITE Karachi Drug License by way of Wholesale No. 0591 valid upto 03-05-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale
	1.4.2	For imported products, please specify one of following: □ Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Salmeterol / Fluticasone Propionate
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each dose contains: Fluticasone Propionate 250mcg & Salmeterol (Eq. to Salmeterol xinafoate) 50mcg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Neuair Discair
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's (60 Doses)
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Bronchodilator+ Corticosteroids
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Oral Inhalation
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Not submitted
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Seretide Accuhaler 50 microgram/250 microgram/ dose inhalation powder, pre-dispensed.

	1.5.10	Dosage form of applied drug Oral Inhalation
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. Submitted
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. Submitted
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Salmeterol API Manufacturer: Inke, S.A. Address: C/ Argent, 1 Area Industrial Del Llobregat Spain-08755 Castellbisbal, Barcelona. Fluticasone Propionate API Manufacturer: M/s Sterling S.P.A, Via Della Carboneria 30 Italy- 06073 Solomeo Di Corciano, Perudia
	Original Legalized CoPP (Certificate#. 2018/3233) issued on 18-09-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency and applied product is not in free	

	sale in exporting country but GMP status of manufacturer i.e., M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey is compliant. valid until 18/09/2020. Original Notarized "Product specific Letter of Authorization" from M/s Neutec Inhaler Ilac San. Ve Tic. A.S,, Turkey declaring M/s The Searle company Limited authorized for registration approval. Dated 16.10.2018 Authorization valid for three years.

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

Firm Submitted CEP (Certification of suitability of European Pharmacopoeia monographs) for Salmeterol API which is verified by EDQM website dated 11-12-2019 link attached:
https://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP?vSelectName=1&Case_TSE=none&vContains=1&vContainsDate=1&vtsubName=Salmeterol&vtsubDateBegin=&vtsubDateBtwBegin=&vtsubDateBtwEnd=&SWTP=1&OK=Search
Firm Submitted CEP (Certification of suitability of European Pharmacopoeia monographs) for Fluticasone propionate API which is verified by EDQM website dated 11-12-2019 link attached:
https://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP?vSelectName=1&Case_TSE=none&vContains=1&vContainsDate=1&vtsubName=fluticasone&vtsubDateBegin=&vtsubDateBtwBegin=&vtsubDateBtwEnd=&SWTP=1&OK=Search

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product

		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data of 24 months (time points 0,6,9,12 & 24 Months) at 300C±65%RH and 6 months at 400C±75%RH for three batches.

Remarks of evaluator:
Firm has submitted three batches long term stability data of 24 months (time points 0,6,9,12 & 24 Months) at 300C±65%RH and 6 months at 400C±75%RH for three batches.
Original Legalized COPP issued by concern regulatory body of exporting country show that applied product is not in free sale in exporting country.
Decision: Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP.

Firm's response: Firm has submitted Original Legalized COPP (Certificate no. 2022/50) valid till 06-01-2024, issued by Ministry of Health, Turkish Medicines and medical Devices Agency, for Neuair Discair 50/250mcg Inhalation Powder declaring following details:

Product License Holder: M/s Neutec Ilac, San. Tic. A.S. , Yildiz Teknik Universitesi Davutpasa Kampusu Teknoloji gelistirme Bolgesi D1 Blok kat: 3 Esenler/Istanbul/Turkey

Manufacturer: M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey **Free Sale status:** Available in country of origin i.e., Turkey. **GMP status of Manufacturer:** Yes
Decision: Approved as per policy of inspections of manufacturer abroad.

326. Neuair Discair Fluticasone Propionate 500mcg & Salmeterol (Eq. to Salmeterol xinafoate) 50mcg Inhalational powder by M/s The Searle company Limited Karachi

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 12001 Dated 16-07-2019 (Rs. 100,000/- Dated 12-07-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s The Searle company Limited, 1st floor N.I.C.L Building Abbasi Shaheed Road off: Shahrah-E-Faisal Karachi-75530
	1.3.2	Name, address and contact details of Manufacturing site. M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	Drug Sale License M/s The Searle company Limited, suit no. 101 1st floor N.I.C Building Abbasi Shaheed Road Karachi Godowns address: F-2/Q SITE Karachi Drug License by way of Wholesale No. 0591 valid upto 03-05-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale
	1.4.2	For imported products, please specify one of following: □ Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Salmeterol / Fluticasone Propionate
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each dose contains: Fluticasone Propionate 500mcg & Salmeterol (Eq. to Salmeterol xinafoate) 50mcg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Neuair Discair
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's (60 Doses)
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Bronchodilator+ Corticosteroids
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Oral Inhalation

	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Not submitted
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Seretide Accuhaler 50 microgram/500 microgram/ dose inhalation powder, pre-dispensed
	1.5.10	Dosage form of applied drug Oral Inhalation
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. Submitted
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. Submitted
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following:

		Name and address of API manufacturer. Salmeterol API Manufacturer: Inke, S.A. Address: C/ Argent, 1 Area Industrial Del Llobregat Spain-08755 Castellbisbal, Barcelona. Fluticasone Propionate API Manufacturer: M/s Sterling S.P.A, Via Della Carboneria 30 Italy- 06073 Solomeo Di Corciano, Perudia
	Original Legalized CoPP (Certificate#. 2018/3234) issued on 18-09-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency and applied product is not in free sale in exporting country but GMP status of manufacturer i.e., M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey is compliant. valid until 18/09/2020. Original Notarized "Product specific Letter of Authorization" from M/s Neutec Inhaler Ilac San. Ve Tic. A.S,, Turkey declaring M/s The Searle company Limited authorized for registration approval. Dated 16.10.2018 Authorization valid for three years.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

Firm Submitted CEP (Certification of suitability of European Pharmacopoeia monographs) for Salmeterol API which is verified by EDQM website dated 11-12-2019 link attached:
https://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP?vSelectName=1&Case_TSE=none&vContains=1&vContainsDate=1&vtsubName=Salmeterol&vtsubDateBegin=&vtsubDateBtwBegin=&vtsubDateBtwEnd=&SWTP=1&OK=Search
Firm Submitted CEP (Certification of suitability of European Pharmacopoeia monographs) for Fluticasone propionate API which is verified by EDQM website dated 11-12-2019 link attached:
https://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP?vSelectName=1&Case_TSE=none&vContains=1&vContainsDate=1&vtsubName=fluticasone&vtsubDateBegin=&vtsubDateBtwBegin=&vtsubDateBtwEnd=&SWTP=1&OK=Search

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted one batche long term stability data of 24 months (time points 0,6,9,12,18 & 24 Months) at 300C±65%RH and two batches stability data of 12 months (time points 0,6,9 & 12Months) at 300C±65%RH and 6 months at 400C±75%RH for three batches.
Remarks of evaluator: Firm has submitted one batches long term stability data of 24 months (time points 0,6,9,12,18 & 24 Months) at 30^0C±65%RH and two batches stability data of 12 months (time points 0,6,9 & 12Months) at 300C±65%RH and 6 months at 40^0C±75%RH for three batches.		

Original Legalized COPP issued by concern regulatory body of exporting country show that applied product is not in free sale in exporting country. **Decision of 293rd meeting:** Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP.
Firm's response: Firm has submitted Original Legalized COPP (Certificate no. 2022/49) valid till 06-01-2024, issued by Ministry of Health, Turkish Medicines and medical Devices Agency, for Neuair Discair 50/500mcg Inhalation Powder declaring following details: **Product License Holder:** M/s Neutec Ilac, San. Tic. A.S. , Yildiz Teknik Universitesi Davutpasa Kampusu Teknoloji gelistirme Bolgesi D1 Blok kat: 3 Esenler/Istanbul/Turkey **Manufacturer:** M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey **Free Sale status:** Available in country of origin i.e., Turkey. **GMP status of Manufacturer:** Yes
Decision: Approved as per policy of inspections of manufacturer abroad.

327. Neuair Discair Fluticasone Propionate 500mcg & Salmeterol (Eq. to Salmeterol xinafoate) 50mcg Inhalational powder by M/s The Searle company Limited Karachi

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 12001 Dated 16-07-2019 (Rs. 100,000/- Dated 12-07-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s The Searle company Limited, 1st floor N.I.C.L Building Abbasi Shaheed Road off: Shahrah-E-Faisal Karachi-75530
	1.3.2	Name, address and contact details of Manufacturing site. M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	Drug Sale License M/s The Searle company Limited, suit no. 101 1st floor N.I.C Building Abbasi Shaheed Road Karachi Godowns address: F-2/Q SITE Karachi Drug License by way of Wholesale No. 0591 valid upto 03-05-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale
	1.4.2	For imported products, please specify one of following: □ Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Salmeterol / Fluticasone Propionate
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each dose contains: Fluticasone Propionate 500mcg & Salmeterol (Eq. to Salmeterol xinafoate) 50mcg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Neuair Discair

	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's (60 Doses)
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Bronchodilator+ Corticosteroids
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Oral Inhalation
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Not submitted
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Seretide Accuhaler 50 microgram/500 microgram/ dose inhalation powder, pre-dispensed
	1.5.10	Dosage form of applied drug Oral Inhalation
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. Submitted
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. Submitted
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.

	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Salmeterol API Manufacturer: Inke, S.A. Address: C/ Argent, 1 Area Industrial Del Llobregat Spain-08755 Castellbisbal, Barcelona. Fluticasone Propionate API Manufacturer: M/s Sterling S.P.A, Via Della Carboneria 30 Italy- 06073 Solomeo Di Corciano, Perudia
	Original Legalized CoPP (Certificate#. 2018/3234) issued on 18-09-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency and applied product is not in free sale in exporting country but GMP status of manufacturer i.e., M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey is compliant. valid until 18/09/2020. Original Notarized "Product specific Letter of Authorization" from M/s Neutec Inhaler Ilac San. Ve Tic. A.S,, Turkey declaring M/s The Searle company Limited authorized for registration approval. Dated 16.10.2018 Authorization valid for three years.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

Firm Submitted CEP (Certification of suitability of European Pharmacopoeia monographs) for Salmeterol API which is verified by EDQM website dated 11-12-2019 link attached:
https://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP?vSelectName=1&Case_TSE=none&vContains=1&vContainsDate=1&vtsubName=Salmeterol&vtsubDateBegin=&vtsubDateBtwBegin=&vtsubDateBtwEnd=&SWTP=1&OK=Search
Firm Submitted CEP (Certification of suitability of European Pharmacopoeia monographs) for Fluticasone propionate API which is verified by EDQM website dated 11-12-2019 link attached:
https://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP?vSelectName=1&Case_TSE=none&vContains=1&vContainsDate=1&vtsubName=fluticasone&vtsubDateBegin=&vtsubDateBtwBegin=&vtsubDateBtwEnd=&SWTP=1&OK=Search

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted

2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
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MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted

	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted one batche long term stability data of 24 months (time points 0,6,9,12,18 & 24 Months) at 300C±65%RH and two batches stability data of 12 months (time points 0,6,9 & 12Months) at 300C±65%RH and 6 months at 400C±75%RH for three batches.
Remarks of evaluator: Firm has submitted one batch long term stability data of 24 months (time points 0,6,9,12,18 & 24 Months) at 30^0C±65%RH and two batches stability data of 12 months (time points 0,6,9 & 12Months) at 30^0C±65%RH and 6 months at 40^0C±75%RH for three batches. Original Legalized COPP issued by concern regulatory body of exporting country show that applied product is not in free sale in exporting country. **Decision of 293rd meeting:** Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP.		
Firm's response: Firm has submitted Original Legalized COPP (Certificate no. 2022/49) valid till 06-01-2024, issued by Ministry of Health, Turkish Medicines and medical Devices Agency, for Neuair Discair 50/500mcg Inhalation Powder declaring following details: **Product License Holder:** M/s Neutec Ilac, San. Tic. A.S. , Yildiz Teknik Universitesi Davutpasa Kampusu Teknoloji gelistirme Bolgesi D1 Blok kat: 3 Esenler/Istanbul/Turkey **Manufacturer:** M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey **Free Sale status:** Available in country of origin i.e., Turkey. **GMP status of Manufacturer:** Yes		
Decision: Approved as per policy of inspections of manufacturer abroad.		

Case no. 06 Registration applications of Import (Veterinary) drugs

328	**Name and address of Applicant**	**M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan**
	Detail of Drug Sale License	Address: **M/s Prix Pharmaceutica,** 26 abbot road Lahore (Godown: Plot NO. 5, Pharmacity, 30Km Multan Road Lahore. Validity: 12/06/2022`
	Name and address of manufacturer	M/s Fatro S.P.A, Via Emilia, 285-40064, Ozzano Emilia (Bo) Italy.
	Name and address of marketing authorization holder	M/s Fatro S.P.A, Via Emilia, 285-40064, Ozzano Emilia (Bo) Italy.
	Name of exporting country	**Italy**
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 75 Dated 14-07-2015
	Fee including differential fee	Rs. 50,000/- Dated 10-07-2015
	Brand Name +Dosage Form + Strength	**ZOOCOLAGOGO C.M. Oral Powder**
	Composition	Each 18gm sachet contains: Rhubarb ……. 9gm Boldo leaf …….. 6gm Condurango ……. 2gm Nux vomica ……. 1gm
	Finished Product Specification	Manufacturer's specification
	Pharmacological Group	Products for alimentary tract and metabolism
	Shelf life	5 years
	Demanded Price	Decontrolled
	Pack size	1's

	International availability	Approved by Italy (Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products)
	Me-too status	N/A
	Stability studies	Firm has submitted long term (60 months) at 25+2oC, 60+5%RH & accelerated (06 months) stability data at 40+ 2oC, 75+ 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP** **Certificate No:** 163/2018/C **Certifying Authority:** Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products **Issue Date:** 19-08-2018 **Free sale in exporting country: Yes** • **GMP of manufacturer:** Yes **GMP Certificate** The GMP certificate (No. NBF/18/2017/V) issued by Ministry of Health - General Directorate of Animal Health and Veterinary Drugs Italy, submitted by the firm and also available at EUDRA GMP database, valid upto 23-02-2020. **Sole Agency Agreement:** Firm has submitted declaration form M/s Fatro S.P.A, Italy wherein M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan has been declared as sole agent in Pakistan for their product "Zoocolagogo C.M. oral powder".
	Remarks of the Evaluator:	
	Decision of 296th meeting: Registration Board deferred the case for following: i. Opinion from H&OTC division regarding the classification of applied formulation. ii. Submission of stability data of the applied product as per Zone IV-a conditions. **iii.** Submission of valid legalized GMP certificate of the finished product manufacturer.	
	Evaluation by PEC: Assistant Director Health & OTC vide letter No. F.8-28/2017 –DD (Health & OTC)The mentioned product is a herbal formulation which contains herbal ingredients including a toxic herbal substance i.e., *Nux Vomica.*	
	Decision: Registration Board referred the case to Committee constituted by Authority to review grey molecules.	

Agenda of Evaluator PEC-VI

Item No. I: Agenda of Evaluator PEC-VI **Case no. 01 Registration applications for local manufacturing of (Human) drugs (Form 5)** **a.** Deferred Cases		
329.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medpectam Injection 500mg
	Composition	Each Vial Contains: Cefoperazone as Sodium…250mg Sulbactam as Sodium…250mg
	Diary No. Date of R& I & fee	Dy.No 15925 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	2Sum Injection 500mg of M/s Sami Pharmaceuticals,

		Karachi (Reg.# 079941)
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue**.**	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore wherein drug product specifications shall also be verified against JP monograph, particularly for the test of "Water content".**	
330.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab.** **28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medpectam Injection 1000mg
	Composition	Each Vial Contains: Cefoperazone as Sodium…500mg Sulbactam as Sodium…500mg
	Diary No. Date of R& I & fee	Dy.No 15926 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulperazon Injection by Pfizer Inc. PMDA Approved
	Me-too status	Ectafin Injection 1gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80028
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue**.**	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore wherein drug product specifications shall also be verified against JP monograph, particularly for the test of "Water content".**	
331.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medpectam Injection 2000mg
	Composition	Each Vial Contains: Cefoperazone as Sodium…1000mg Sulbactam as Sodium…1000mg
	Diary No. Date of R& I & fee	Dy.No 15927 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia

	Me-too status	Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue**.**	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore wherein drug product specifications shall also be verified against JP monograph, particularly for the test of "Water content".**	
332.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medixime DS 100mg/5ml suspension
	Composition	Each 5ml contains: Cefixime as Trihydrate…100mg
	Diary No. Date of R& I & fee	Dy.No 153931 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Stlicef Dry Suspension 100mg/5ml of Treat Pharma
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue**.**	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.**	
333.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab.** **28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medixime DS 200mg/5ml suspension
	Composition	Each 5ml contains: Cefixime as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 153932 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Stlicef Dry Suspension 200mg/5ml of Treat Pharma

	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue**.**	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.**	
334.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab.** **28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Mediximе Capsule 400mg
	Composition	Each capsule contains: Cefixime as Trihydrate…400mg
	Diary No. Date of R& I & fee	Dy.No 15928 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Spanix Capsule by Neomedix Pharma
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension, capsule (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue**.**	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.**	
335.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab.** **28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medipim Injection 1000mg
	Composition	Each Vial Contains: Cefepime as Hcl …1000mg
	Diary No. Date of R& I & fee	Dy.No 15921 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nuxipim 1g Injection of Bosch
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section

	Decision of 296th : Deferred for consideration on its turn according to the queue**.**	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.**	
336.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab.** **28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medipim Injection 500mg
	Composition	Each Vial Contains: Cefepime as Hcl …500mg
	Diary No. Date of R& I & fee	Dy.No 15921 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nuxipim 500mg Injection of Bosch
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue**.**	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.**	
337.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab.** **28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medadin Injection 500mg
	Composition	Each Vial Contains: Ceftazidime as pentahydrate…500mg
	Diary No. Date of R& I & fee	Dy.No 15923 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ceftaz by Pharmedic
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue.	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.**	

338.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medadin Injection 250mg
	Composition	Each Vial Contains: Ceftazidime as pentahydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 15992 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ceftaz by Pharmedic
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue.	
	Decision: Approved. Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.	
339.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medodoxime DS 50mg/5ml suspension
	Composition	Each 5ml contains: Cefpodoxime as Proxetil…50mg
	Diary No. Date of R& I & fee	Dy.No 15929 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Qink Dry Suspension of M/s Wilshire Laboratories
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue.	
	Decision: Approved. Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.	
340.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore**

	Brand Name +Dosage Form + Strength	Medodoxime DS 100mg/5ml suspension
	Composition	Each 5ml contains: Cefpodoxime as Proxetil…100mg
	Diary No. Date of R& I & fee	Dy.No 15930 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Qink Dry Suspension of M/s Wilshire Laboratories
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue.	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.**	
341.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt** **Contract manufacturing from** **M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Cefamed Injection 250mg IM
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Diary No. Date of R& I & fee	Dy.No 15930 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Unixone Injection (ceftriaxone Sodium) 250mg IM by Caliph Pharmaceuticals (Pvt.) Ltd. Reg. No. 82556
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision of 296th : Deferred for consideration on its turn according to the queue.	
	Decision: Approved. **Registration Board Authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore.**	
342.	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Hb-Ron Syrup 60 ml, 120 ml
	Composition	Each 5 ml contain: Iron (III) hydroxide polymaltose complex eq. to elemental iron…….50mg Folic acid…….0.35mg
	Diary No. Date of R& I & fee	Dy No. 1683: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Iron in combination with folic acid

	Type of Form	Form-5
	Finished product Specification	The firm has claimed manufacturer's specification
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Poly-F Syrup. Reg. No. 064045
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no. S-66, 5200 Bottles was "Ordered not to dispose of" due to poor sanitation & hygiene conditions in the oral liquid filling area
	Remarks of the Evaluator.(VI)	The firm revised to the quantity of Folic acid from 0.50 mg to 0.35mg without submission of fee.
	Previous Decision:	The board in its 287th meeting deferred the case for: • Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. • Submission of fee for revision of formulation
	Evaluation by PEC	The firm submitted inspection report dated 11.12.2019, wherein resumption of production has been recommended in oral liquid syrup section. • The firm shall submit fee for revision of strength of API
	Decision of 295th	Deferred for submission of fee for revision of strength of API.
	Response of the Firm	Firm has submitted fee of Rs. 7,500/- dated 15-02-2022 vide slip no. 965174160117 to revise quantity of folic acid from 0.50 mg to 0.35mg as per registered me-too.
	Decision: Approved with Innovator's specifications. Registration Board further decided that registration letter will be issued after submission of differential fee that is Rs. 22,500/- for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
343.	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Metasone GM/Metacort Plus Cream
	Composition	Each gram cream contains: Betamethasone (as valerate)……1.2mg Gentamycin (as sulfate)…….1mg Miconazole (as nitrate)……20mg
	Diary No. Date of R& I & fee	Dy No. 1686: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics and antifungal
	Type of Form	Form-5
	Finished product Specification	The firm has claimed manufacturer's specification
	Pack size & Demanded Price	20g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of

		product Mondison 4mg/5ml (50ml) Syrup, Batch no. S-66, 5200 Bottles was "Ordered not to dispose of" due to poor sanitation & hygiene conditions in the oral liquid filling area
	Remarks of the Evaluator.(VI)	. • The brand name shall be changed
	Previous Decision:287th	Deferred for the following: • Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm
	Evaluation by PEC	Firm has submitted evidence of submission of fee of Rs.7,500/- dated 11-02-2022 vide slip no. 26027666328, to revise the quantity of Betamethasone (as valerate) from 1.2 mg to 1mg as per me-too product Mycona-GB Cream in which 0.1% w/w betamethasone valerate has been used along Gentamicin (as sulfate) 0.1% w/w and Miconazole nitrate 2% w/w. • Firm submitted inspection report dated 11-12-2019, wherein resumption of production has been recommended in oral liquid syrup section. Status of having cream/ointment section could not have confirmed from the said inspection report. • Further, Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.	

Case no. 04 Registration applications of newly granted DML or New section (Veterinary)

a. New DML /section

b. Deferred Cases

344.	**Name and address of manufacturer / Applicant**	**M/s Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Isodon Injection
	Composition	Each ml contains: Isoflupredon Acetate….....2 mg
	Diary No. Date of R& I & fee	Dy no 34783, dated 30-12-2020, Rs 20,000/-
	Pharmacological Group	Steroid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specification
	Pack size & demanded price	50 ml; Decontrolled
	Me-too status	Predef 2X Injection (Reg. # 019978) by Bela-Pharm Gmbh & Co.,KG, Germany. Imported by Ghazi Brothers
	GMP status	New Section Veterinary Liquid Injection Vial (Steroid)
	Remarks of the Evaluator -VI	• Clarification shall be submitted regarding applied dosage form whether Injectable solution & Injectable suspension since submitted me too reference is of Injectable suspension.
	Decision: 297th Deferred for clarification regarding applied dosage form whether Injectable solution & Injectable suspension since submitted me too reference is of Injectable suspension.	
	Evaluation by PEC VI: The firm submitted that	

	"Isodon injection 50ml shall be injectable suspension dosage form as per me too reference'' The firm has did not submit fee for correction and change in master formulation**.**
	Decision of 316th: Deferred for submission of master formulation. Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
	Remarks: The firm has submitted Fee Rs 30,000 Deposit Slip No. 65513348856 and changed the formulation from Injectable solution to Injectable suspension.
	Decision: Approved.

Case no. 08 Registration applications of import (Human) drugs on Form 5F

b. New Cases

345.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hiranis Pharmaceuticals (Pvt) Ltd**
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt) Ltd Plot E-145-149, North western industrial zone, Port Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26925 dated 29/09/2021
	Details of fee submitted	PKR 30,000/-: dated 11/08/2021
	The proposed proprietary name / brand name	Logican Capsule 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluconazole ….50mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Reference to Finished product specifications	BP
	Proposed Pack size	7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Diflucan Capsule 50mg M/s Pfizer Laboratories MHRA Approved.
	For generic drugs (me-too status)	Diflucan Capsule 50mg Reg. No. 011827 by M/s Pfizer
	GMP status of the Finished product manufacturer	DML by way of formulation No. 000785 dated 03-02-2019
	Name and address of API manufacturer.	**Fluconazole** M/s. Pioneer Laboratories India Pvt. Ltd. Address: 94A, 95B & 96A Industrial Area No.1, A.B. Road Dewas (M.P.) India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description

		of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The official monograph is present in United States Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Fluconazole:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: **Fluconazole:** FLC/FD/03/1204-05, FLC/FD/02/1104-05, FLC/FD/01/0004-05
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is **Diflucan 50mg Capsule** by **M/s Pfizer Laboratories.** CDP has been performed against the same brand that is **Diflucan 50mg Capsule** by **M/s Pfizer Laboratories** in Acid media (0.1 N HCL) & Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). F_1 & F_2 values both are within the range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	**Fluconazole** M/s. Pioneer Laboratories India Pvt. Ltd. Address: 94A, 95B & 96A Industrial Area No.1, A.B. Road Dewas (M.P.) India.
API Lot No.	**Fluconazole:** FLC/FD/29/02/18-19
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (1×7's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		**TF-210819**	**TF-220819**	**TF-230819**
Batch Size		1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date		01-2020	01-2020	01-2020
Date of Initiation		21-08-2019	21-08-2019	21-08-2019
No. of Batches		03	
Administrative Portion			
25.	Reference of previous approval of applications with stability study data of the firm (if any)	Etoxib 90mg Tablet Etoxib 120mg Tablet Approved in 294th minutes of meeting of DRB	
26.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Fluconazole:** Copy of DML No. 25/5/2010 issued by Food and Drugs Administration Madhya Pradesh	
27.	Documents for the procurement of API with approval from DRAP (in case of import).	• Attested invoice from ADC attached for Fluconazole Invoice No. RPLPL/18-19/0277	
28.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of batches along with chromatograms, raw data sheets, COA and summary data sheets	
29.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software 21 CFR and copies of audit trail on testing of drug product.	
30.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Remarks of Evaluator:			
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**			
365.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hiranis Pharmaceuticals (Pvt) Ltd**	
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt) Ltd Plot E-145-149, North western industrial zone, Port Qasim, Karachi.	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales	

	Dy. No. and date of submission	Dy.No 26925 dated 29/09/2021
	Details of fee submitted	PKR 30,000/-: dated 11/08/2021
	The proposed proprietary name / brand name	Logican Capsule 200mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluconazole ……200mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	Reference to Finished product specifications	BP
	Proposed Pack size	4's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Diflucan Capsule 200mg M/s Pfizer Laboratories MHRA Approved.
	For generic drugs (me-too status)	Diflucan Capsule 200mg; Reg. No. 011829 by M/s Pfizer
	GMP status of the Finished product manufacturer	DML by way of formulation No. 000785 dated 03-02-2019
	Name and address of API manufacturer.	**Fluconazole** M/s. Pioneer Laboratories India Pvt. Ltd. Address: 94A, 95B & 96A Industrial Area No.1, A.B. Road Dewas (M.P.) India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The official monograph is present in United States Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Fluconazole:** Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Fluconazole:** FLC/FD/01/0004-05, FLC/FD/02/0004-05, FLC/FD/03/0004-05.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure

		(including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is **Diflucan 200mg Capsule** by **M/s Pfizer Laboratories** CDP has been performed against the same brand that is **Diflucan 200mg Capsule** by **M/s Pfizer Laboratories** in Acid media (0.1 N HCL) & Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). F_1 & F_2 values both are within the range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Fluconazole** M/s. Pioneer Laboratories India Pvt. Ltd. Address: 94A, 95B & 96A Industrial Area No.1, A.B. Road Dewas (M.P.) India.		
API Lot No.	**Fluconazole:** FLC/FD/29/02/18-19		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (1×4's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	**TF-070819**	**TF-080819**	**TF-090819**
Batch Size	1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	07-08-2019	07-08-2019	07-08-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Etoxib 90mg Tablet Etoxib 120mg Tablet Approved in 294th minutes of meeting of DRB
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Fluconazole:** Copy of DML No. 25/5/2010 issued by Food and Drugs Administration Madhya Pradesh
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Attested invoice from ADC attached for Fluconazole Invoice No. RPLPL/18-19/0277
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of batches along with chromatograms, raw data sheets, COA and summary data sheets

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software 21 CFR and copies of audit trail on testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

346.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.**
	Name, address of Manufacturing site.	M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24845 dated 08-09-2021
	Details of fee submitted	PKR 30,000/-: dated 24/05/2021
	The proposed proprietary name / brand name	**Rigix Oral Solution (Banana flavor)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cetirizine HCl…….5mg
	Pharmaceutical form of applied drug	Clear colorless liquid with characteristic Banana flavor and odor.
	Pharmacotherapeutic Group of (API)	Antihistamine for systemic use
	Reference to Finished product specifications	BP Specification Shelf life claimed is 24months.
	Proposed Pack size	60ml and 120ml
	Proposed unit price	Rs. 78.09/- for 60ml Rs. 124.17/- for 120ml
	The status in reference regulatory authorities	Cetirizine Hydrochloride 5mg/5ml by Chain Drug Consortium LLC (Premier Value), USA.
	For generic drugs (me-too status)	Zyrtec 5mg/5ml Oral Solution by M/s GlaxoSmithKline. Reg. No. 016937
	GMP status of the Finished product manufacturer	Renewal of GMP on 17-06-2021. Renewal of DML on 30-06-2020. Firm has Oral Liquid (general) section.

	Name and address of API manufacturer.	**Cetirizine Hydrochloride:** M/s PRAVEEN LABORATORIES PVT. LTD, India, Block No. 206, Village: Jolwa, Taluka: Palsana Dist.: Surat, Gujarat, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cetirizine Hydrochloride is present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**API Stability study conditions:** **Real time:** 25°C ± 2°C / 60% ± 5%RH for 60 months 30°C ± 2°C / 65% ± 5%RH for 60 months **Accelerated:** 40°C ± 2°C / 75% ± 5% RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is carried on with **Zyrtec Oral Solution** manufactured by **M/s GSK Pakistan**
	Analytical method validation/verification of product	Method verification studies have submitted including System suitability, accuracy, precision, specificity, Limit of detection, Limit of quantification.

STABILITY STUDY DATA	
Manufacturer of API	**Cetirizine Hydrochloride:** M/s PRAVEEN LABORATORIES PVT. LTD, India, Block No. 206, Village: Jolwa, Taluka: Palsana Dist.: Surat, Gujarat, INDIA.
API Lot No.	Cetirizine Hydrochloride: MK40119136, MK40119137, MK40119138 & MK40119139
Description of Pack (Container closure system)	Amber glass bottle with ALU fitted with wad. Each bottle is packed in printed carton.
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5% RH Long Term: 30°C ± 2°C / 65% ± 5%RH 25°C ± 2°C / 60% ± 5%RH

Time Period	Real time: 18 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Intermediate: 0, 6, 9, 12 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	TR-640	TR-641	TR-642
Batch Size	25000	25000	25000
Manufacturing date	10-2020	10-2020	10-2020
Date of Initiation	27-10-2020	27-10-2020	27-10-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The board approved Glyzia-XR Tablet 50/500m of M/s AGP limited B-23, SITE, Karachi in 285th meeting held in October 2018. As per minutes, HPLC is 21 CFR compliant and have audit trails.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Cetirizine Hydrochloride:** Copy of GMP certificate No. SGMP/21092927 issued by Food and Drug Control Administration, India, valid till 09th Oct 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	ADC Attested Karachi invoice no Ex/060 date 1-1-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 3 batches with raw data sheets, COA, and chromatograms have been submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing was submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) was submitted

Remarks of Evaluator:

Short coming	**Replies**
a) 2.3.P.8/ 3.2.P.8 Stability. The storage condition "Do not store above 25C°" does not meet zone IV a condition. Please Justify.	• The storage conditions will be "Do not store above 30C°". • We have conducted stability studies of our product on Zone IV-A (30°C ± 2°C / 65 ± 5% RH) and by mistake we have skipped 3rd month stability testing point but we have performed 6th month, 9th month and 12th months and 18th month stability studies and results shows that the product is stable. • We have also performed accelerated stability studies for 0, 3 & 6 months, the results are also in compliance with specifications. • We assure you that we will continue the stability studies up to the shelf life of 24 months and submit the data at DRAP. • Valid copy of GMP certificate of API manufacturer i.e. M/s PRAVEEN

b) Approval of valid API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin is required.	LABORATORIES PVT. LTD, India, Block No. 206, Village: Jolwa, Taluka: Palsana Dist.: Surat, Gujarat, INDIA. Valid till 19-9-2023. Certificate is issued by Food and Drug Control Administration.

Decision: Approved.

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

347.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	Indus Pharma (Pvt) Ltd. Plot No. 26-27, 64-67, Sector-27, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24851 dated 08-09-2021
	Details of fee submitted	PKR 75,000/-: dated 02-09-2021
	The proposed proprietary name / brand name	**Dowmoxi Infusion 400mg/250ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Moxifloxacin Hydrochloride eq. to Moxifloxacin……400mg
	Pharmaceutical form of applied drug	Infusion
	Pharmacotherapeutic Group of (API)	Fluroquinolone antibiotic
	Reference to Finished product specifications	As per Innovator's Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product is registered in USFDA, with brand name **"AVELOX"** by Bayer Healthcare Pharmaceuticals Inc.
	For generic drugs (me-too status)	**Mob Infusion 400mg/250ml by Indus Pharma** (Registration No. 047428)
	GMP status of the Finished product manufacturer	GMP certificate issued 18-12-2020
	Name and address of API manufacturer.	M/s Enaltec Labs Pvt Ltd., **Address:** Plot No. 825,826,827 Industrial Area, Sector 3, Pthampur Dist Dhar, MP, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO

		QOS PD template.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence of Doxmoxi Infusion has been compared with the comparator product Avelox Infusion 400mg/250ml by Bayer Healthcare.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Enaltec Labs Pvt Ltd., **Address:** Plot No. 825,826,827 Industrial Area, Sector 3, Pthampur Dist Dhar, MP, India.		
API Lot No.	EL-05/L011/20022		
Description of Pack (Container closure system)	250ml Clear Glass Vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	MB-579	MB-580	MB-581
Batch Size	2000 Vials	2000 Vials	2000 Vials
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	30-12-2020	30-12-2020	30-12-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm (M/s Indus Pharma Karachi) has referred to their product Canazin Tablets 300mg which was approved in 289th Meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML Certificate for Enaltec Labs Pvt Ltd. issued by Licensing Authority Food and Drugs Administration Madhya Pradesh & valid up to 30-10-2023 is submitted. Copy of GMP Certificate for Enaltec Labs Pvt Ltd. issued by Licensing Authority Food and Drugs

		Administration Madhya Pradesh & valid up to 25-12-2023 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted (Invoice No. EXP-I-2021-00206) dated 27-11-2020 specifying import of Moxifloxacin cleared by DRAP Karachi office dated 07-12-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
348.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited,7-Jail Road, Quetta
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited,7-Jail Road, Quetta
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27885 dated 08/10/2021
	Details of fee submitted	PKR 30,000/-: dated 15/09/2021
	The proposed proprietary name / brand name	Angiolo Tablet 100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Losartan Potassium, ……100mg
	Pharmaceutical form of applied drug	film coated Tablets
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor antagonist (Anti-hypertensive)
	Reference to Finished product specifications	USP
	Proposed Pack size	2×10's (20's)
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	AURO-LOSARTAN Tablet 100mg by M/s Auro Pharma Inc. HEALTH CANADA Approved.
	For generic drugs (me-too status)	Eziday Tablet 100mg by Werrick Pharmaceutical Pakistan (Pvt.) Ltd., Reg. No. 056103
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Losartan Potassium is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Cozaar Tablets by M/s Merck Sharp & Dohme Limited. CDP has been performed against the same brand that is Cozaar Tablets by M/s Merck Sharp & Dohme Limited in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Linhai, Zhejiang 317016, China		
API Lot No.	C5455-20-045		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	10000 Tablets	10000 Tablets	10000 Tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	10-2020	10-2020	10-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Acidex 60mg Capsule Dexlansoprazole was approved in 312th Registration Board meeting. 1) Compliance Record of HPLC software 21CFR & audit trail reports on product testing were present
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20170049 issued by CFDA valid till 15/01/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	ADC Invoice No: HH20201310, 11-June-2020 is submitted wherein the permission to import APIs (Losartan Potassium) for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers

Remarks of Evaluator:

Decision: Approved.

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

349.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Werrick Pharmaceuticals, Islamabad**
	Name, address of Manufacturing site.	**Name: M/s** Werrick Pharmaceuticals, Plot# 216-217, Sector I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20683, 20-08-2020
	Details of fee submitted	PKR 20,000/-: 29-07-2020
	The proposed proprietary name / brand name	**Gluset Plus XR Tablets 100/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: **Sitagliptin (as Phosphate monohydrate)**: 100mg **Metformin HCl**: 1000mg
	Pharmaceutical form of applied drug	Extended Release Film Coated Tablets
	Pharmacotherapeutic Group of (API)	**Sitagliptin (as Phosphate monohydrate):** Oral Antidiabetic Drug (Dipeptidyl Peptidase-4) **Metformin HCl:**Oral Antidiabetic Drug (Biguanide)
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	14's, 20's, 30's
	Proposed unit price	As Per S.R.O
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	Tagipmet XR Tablets 100/1000mg
	GMP status of the Finished product manufacturer	License granted on 09/11/2018 Tablet (General & General Antibiotic) section approved. Applied for renewal of GMP.
	Name and address of API manufacturer	**Sitagliptin (as Phosphate monohydrate)**:M/s Zhejiang Tianyu Pharmaceuticals Co. LtdNo.15, Dongai 5th Avenue, Zhejiang Provincial chemical and Medical Raw Materials BaseLinhai Zone , TaizhouCity, Zhejiang Province, China. **Metformin HCl**: M/s AbhilashaPharmaPvt. Ltd Plot# 1408, 1409 G.I.D.C Estate Ankleshwar—393002 Gujarat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, assay, tests for related substance and specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug substance.
	Stability Studies	Stability study conditions: **Sitagliptin phosphate Monohydrate:** Real time: 30°± 2°C &65± 5% RH for 18 months Accelerated: 40°± 2°C & 75± 5% RH for 6 months Batches: (12300-160101, 12300-160102, 12300-160103) **Metformin HCl:** Real time: 30°± 2°C &65± 5% RH for 60 months Accelerated: 40°± 2°C & 75± 5% RH for 6 months Batches: (MET099/13 MET100/13, MET101/13)
	Module-III (Drug Product)	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Pharmaceutical Equivalence Process validation protocol, Finished product analytical method validation report & stability studies data.
	Pharmaceutical equivalence and CDP	Pharmaceutical Equivalence has been established against the Brand Leader Janumet XR Tablets 100/1000mg Batch No. RO28366 by Merck & CO. USA by performing quality tests (Identification, Assay, and Dissolution). CDP has been performed against the same brand that is Janumet XR Tablets 100/1000mg by Merck & CO. USA in Phosphate Buffer (pH 6.8), Acetate Buffer (pH 4.5) &Acid media (0.1N HCl).
	Analytical method validation/verification of product	Method Validation studies have submitted including System suitability, specificity, linearity, limit of detection (LOD) and limit of quantification (LOQ), accuracy, precision and robustness.

STABILITY STUDY DATA

Manufacturer of API **Sitagliptin (as Phosphate monohydrate)**: **Metformin HCl**:	M/s Zhejiang Tianyu Pharmaceuticals Co. Ltd No.15, Dongai 5th Avenue, Zhejiang Provincial chemical and Medical Raw Materials Base Linhai Zone , Taizhou City, Zhejiang Province, China. M/s Abhilasha Pharma Pvt. Ltd Plot# 1408, 1409 G.I.D.C Estate Ankleshwar—393002 Gujarat, India		
API Lot No.	Sitagliptin (as Phosphate monohydrate):12301-17030101 Metformin HCl: MET121/16		
Description of Pack (Container closure system)	Alu-Alu Blister Strip packed in card box of unit carton of 14's Tablets 500U/C further packed in corrugated box		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TRIAL# 01	TRIAL# 02	TRIAL# 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	09-2018	09-2018	09-2018
Date of Initiation	25-09-2018	26-09-2018	27-09-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Registration Board decided to approve registration of Wardy Tablets 25mg (Empagliflozin)of M/s. Werrick Pharmaceuticals in 316th meeting. According to the report following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin (as Phosphate monohydrate)**: GMP Certificate for M/s Zhejiang Tianyu Pharmaceuticals Co. Ltd, China issued by China Food & Drug Administration valid Up to 28-03-2022. **Metformin HCl**: GMP Certificate no. 19081546. for M/s Abhilasha Pharma Pvt. Ltd, India issued by India Food & Drug Administration valid Up to 25-08-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice **Sitagliptin (as Phosphate monohydrate)**: Invoice No. TY117434 dated: 05-06-2017 cleared by DRAP Islamabad office dated: 23-06-2017 specifying import. 2Kg Sitagliptin (Batch # 12301-17030101). **Metformin HCl**: Invoice No. Exp-023/2016-17 dated: 08-12-2016 cleared by DRAP Islamabad office dated: 27-12-2016 specifying import 500 kg Metformin HCl (Batch # MET 121/16).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers

Remarks of the Evaluator:

Sr.#	Section#.	Observations/Deficiencies/Short-comings	Remarks of the firm
A.	1.6.5	Valid GMP certificate of M/s Abhilasha Pharma Ltd. India is required.	GMP Certificate for M/s Abhilasha Pharma Pvt. Ltd, India issued by India Food & Drug Administration valid Up to **25-08-2022**.
B.	3.2.S.4	Copies of Drug Substance specifications and analytical procedures used for routine testing of Drug Substance (API) by Drug Product manufacturer is required. Validation of analytical procedures, Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non- compendial Drug Substance(s) shall be submitted.	The firm has submitted Drug Substance specifications and analytical procedures used for routine testing of Drug Substance (API) by the firm. Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the firm for both compendial Drug Substance(s) are supported by attested respective including chromatograms, Method verification report, and summary data sheets.
C.	3.2.S.4.4	A discussion and justification should be provided for any incomplete analyses of the drug substances / API by Drug Product manufacturer	For **Metformin HCl B.P**& **Sitagliptin** (as Phosphate monohydrate) **USP** all tests including impurities are performed as per

			British Pharmacopeia and United States Pharmacopeia, respectively by the Drug product manufacturer.
E.	3.2.S.7	Metformin HCL: The results of the accelerated and long- term stability studies should be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted.	The firm has submitted summarized results of the accelerated and long-term stability studies. Storage condition for long-term stability studies are 30°C ± 2°C / 65% ± 5%RH& for accelerated stability studies are 40°C ± 2°C / 75% ± 5%RH.
F.	3.2.P.5.3	Specificity parameter has been performed by injecting the blank and standard solution. Whereas USP chapter < 1225>&ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation.	The firm has submitted justification for Specificity parameter according to USP chapter < 1225>&ICH Q2 (R1) guidelinesby spiking the drug substance with appropriate levels of impurities supported by attested chromatograms.
L.	Record of Digital Data Logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required.		Submitted

Decision: Approved.

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

350.	Name, address of manufacture/ Applicant	M/s Werrick Pharmaceuticals, Plot # 216-217, Sector I-10/3 Industrial Area ,Islamabad
	Brand Name +Dosage Form+ Strength	Sotalo Tablets 160mg
	Composition	Each Tablet Contains: Sotalol as HCl …….. 160mg
	Diary No. Date of R& I & fee	Dy. No 3444 dated 07-09-2017 (form 5 D) Rs.50,000/- (Exemption date)dated: 29/01/2021 ,
	Pharmacological Group	Non-Selective beta-adrenergic receptor blocker
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Betapace Tablets by USFDA Approved.
	Me-too status	Nibsol Tablets 160mg by Wilson's Pharmaceuticals
	GMP status	New License granted on 22/08/2022
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Sotalo Tablets 160mg
Name of Manufacturer	M/s Werrick Pharmaceuticals, Plot # 216-217, Sector I-10/3 Industrial Area ,Islamabad
Manufacturer of API	M/s Neuland Laboratories Ltd, Sanali Info Park, A Ground Floor, 8-2-120/113, RoadNo.2, Banjara Hills, Hyderabad-500034, Telangana, India.
API Lot No.	SH11117091
Description of Pack (Container closure system)	Alu-Alu 10's, 20's & 30's Tablets per Pack
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 1,2,3,4,6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	11-05-2018	11-05-2018	11-05-2018
No. of Batches	03		
Date of Submission	Exemption date : 29/01/2021		

DOCUMENTS/DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Registration Board decided to approve registration of Wardy Tablets 25mg (Empagliflozin) of M/s. Werrick Pharmaceuticals in 316th meeting. According to the report following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Sotalol HCl:** **API:** Copy of COA (Batch#SH11117091) From Neuland Laboratories Ltd. Banjara Hills, Hyderabad-500034, Telangana, India. **FPP:** Copy of COA submitted
3.	Method used for analysis of API from both API Manufacturer & Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer & Finished Product Manufacturer has been submitted.
4.	Stability study data of API from API manufacturer	Real time data submitted at 30 and 65 for 60months and Accelerated time :- 40 and 75% for 6 months.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 1199/E1/2019 issued by WHO valid till 30/06/2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice No. NEU/UI/EXP/00430/ Dated 19-02-2018
7.	Protocols followed for conduction of stability studies.	Protocols followed for conduction of stability studies was submitted
8.	Method used for analysis of FPP	The firm has submitted photocopies of following: FPP Test/Analysis Method & FPP Specifications
9.	Drug-excipients compatibility studies (where applicable)	Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.
10.	Complete batch manufacturing record of three stability batches	BMR was provided.
11.	Record of comparative dissolution data (where applicable)	Exemption claimed as Reference product is not available in Pakistan.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted photocopy of Batch Manufacturing Record of three stability batches such as. Sotalo Tablets 160mg Batch No. | Date of Mfg. | Batch Size T-01 | 04-2018 | 1500 Tablets

		T-02 | 04-2018 | 1500 Tablets T-03 | 04-2018 | 1500 Tablets
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved. • **Registration Board further decide that registration letter will be issued upon submission of CDP studies against the innovator drug product.** • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

351.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23843 dated 31-08-2021
	Details of fee submitted	Rs.30,000/- dated 12-08-2021 Slip no. 2710858202
	The proposed proprietary name / brand name	**Curin 97mg/103mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril…….97mg Valsartan….103mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	neprilysin inhibitors / angiotensin receptor blockers (ARBs)
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto 97mg/103mg Tablet of Novartis Europharm limited. (EMA approved)
	For generic drugs (me-too status)	Sacvin 97mg/103mg Tablet of Pharm Evo Pvt Ltd.

	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 11-02-2019, was valid till 09-02-2022. Request for GMP inspection R&1 date: 22-12-2021 is provided.
	Name and address of API manufacturer.	**Sacubitril/Valsartan:** SHANDONG BOYUAN PHARMACEUTICA; CO., LTD MANUFACTURING FACILITY Qiangjin street , jibei economic development zone, jinan city, Shandong province, china, 250101
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C, RH: 65% ± 5% for 24 months Accelerated: 40°C ± 2°C, RH: 75% ± 5% for 6 months Batches: (16091301, 16091801, 16092501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence and comparative dissolution profile of their developed formulation Curin 97mg/103mg Tablet (B # NDP-223) with reference product Entresto 97mg/103mg Tablet (B #TCL-04) of M/s Novartis pharmaceutical Pvt. Ltd. in pH 1.2, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of CDP showed that release profile of both test and comparator products were comparable. The values for f2 factor are in the acceptable range.

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API	**Sacubitril/Valsartan:** M/s SHANDONG BOYUAN PHARMACEUTICA; CO., LTD MANUFACTURING FACILITY Qiangjin street , jibei economic development zone, jinan city, Shandong province, china, 250101		
API Lot No.	2020022601		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (1×14's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD 223 T-01	NPD 223 T-02	NPD 223 T-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	16-03-2021	16-03-2021	16-03-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 286th meeting decided to approve registration of Sofovir-V 400mg/100mg Tablet. Inspection date: 5 & 15 October, 2018 The report shows that: The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted GMP certificate for M/s Shandong Boyuan Phar Shandong Boyuan Pharmaceutical; Co., Ltd, China issued by Food and Drug Administration China. The certificate is valid till 18-05-2023	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of ADC for the import of Sacubitril/Valsartan (2.5 Kg, dated 08-07-2020	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.	

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		
352.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23842 dated 31-08-2021
	Details of fee submitted	PKR 30,000/-: dated 12/08/2021 Slip no. 9261596717
	The proposed proprietary name / brand name	**Curin 49mg/51mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril…….49mg Valsartan……..51g
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	neprilysin inhibitors / angiotensin receptor blockers (ARBs)
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto 49mg/51mg Tablet of Novartis Europharm limited. (EMA approved)
	For generic drugs (me-too status)	Sacvin 49mg/51mg Tablet of Pharm Evo Pvt Ltd.
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 11-02-2019, was valid till 09-02-2022. Request for GMP inspection R&1 date: 22-12-2021 is provided.
	Name and address of API manufacturer.	**Sacubitril/Valsartan:** SHANDONG BOYUAN PHARMACEUTICA; CO., LTD MANUFACTURING FACILITY Qiangjin street , jibei economic development zone, jinan city, Shandong province, china, 250101
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties,

		solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C, RH: 65% ± 5% for 24 months Accelerated: 40°C ± 2°C, RH: 75% ± 5% for 6 months Batches: (16091301, 16091801, 16092501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence and comparative dissolution profile of their developed formulation Curin 49mg/51mg Tablet (B # NDP-222) with reference product Entresto 49mg/51mg Tablet (B #TDE-93) of M/s Novartis pharmaceutical Pvt. Ltd. in pH 1.2, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of CDP showed that release profile of both test and comparator products were comparable. The values for f2 factor are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	**<u>Sacubitril/Valsartan:</u>** SHANDONG BOYUAN PHARMACEUTICA; CO., LTD MANUFACTURING FACILITY Qiangjin street , jibei economic development zone, jinan city, Shandong province, china, 250101
API Lot No.	2020022601
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (1×14's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD 222 T-01	NPD 222 T-02	NPD 222 T-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	14-03-2021	14-03-2021	14-03-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 286th meeting decided to approve registration of Sofovir-V 400mg/100mg Tablet. Inspection date: 5 & 15 October, 2018 The report shows that: The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted GMP certificate for M/s Shandong Boyuan Phar Shandong Boyuan Pharmaceutica; Co., Ltd, China issued by Food and Drug Administration China. The certificate is valid till 18-05-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of ADC for the import of Sacubitril/Valsartan (2.5 Kg, dated 08-07-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks OF Evaluator:		
353.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot # 22-23 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23841 dated 31-08-2021
	Details of fee submitted	PKR 30,000/-: dated 12/08/2021 Slip no. 71384658290
	The proposed proprietary name / brand name	**Curin 24mg/26mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril…….24mg Valsartan……..26g
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	neprilysin inhibitors / angiotensin receptor blockers (ARBs)
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto 24mg/26mg Tablet of Novartis Europharm limited. (EMA approved)
	For generic drugs (me-too status)	Sacvin 24mg/26mg Tablet of Pharm Evo Pvt Ltd.
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 11-02-2019, was valid till 09-02-2022. Request for GMP inspection R&1 date: 22-12-2021 is provided.
	Name and address of API manufacturer.	**Sacubitril/Valsartan:** SHANDONG BOYUAN PHARMACEUTICA; CO., LTD MANUFACTURING FACILITY Qiangjin street , jibei economic development zone, jinan city, Shandong province, china, 250101
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

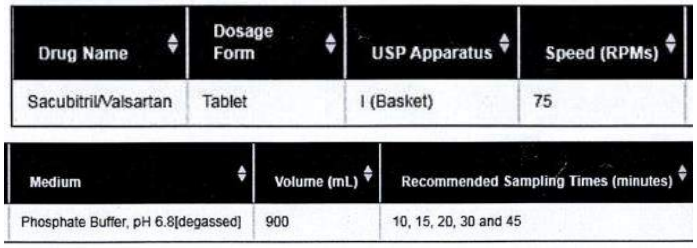
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C, RH: 65% ± 5% for 24 months Accelerated: 40°C ± 2°C, RH: 75% ± 5% for 6 months Batches: (16091301, 16091801, 16092501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence and comparative dissolution profile of their developed formulation Curin 24mg/26mg Tablet (B # NDP-218) with reference product Entresto 24mg/26mg Tablet (B #TCR-37) of M/s Novartis pharmaceutical Pvt. Ltd. in pH 1.2, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of CDP showed that release profile of both test and comparator products were comparable. The values for f2 factor are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**<u>Sacubitril/Valsartan:</u>** SHANDONG BOYUAN PHARMACEUTICA; CO., LTD MANUFACTURING FACILITY Qiangjin street , jibei economic development zone, jinan city, Shandong province, china, 250101		
API Lot No.	2020022601		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (1×14's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	NPD 218 T-06	NPD 218 T-07	NPD 218 T-08
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	02-01-2021	02-01-2021	02-01-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board

		in 286th meeting decided to approve registration of Sofovir-V 400mg/100mg Tablet. Inspection date: 5 & 15 October, 2018 The report shows that: The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted GMP certificate for M/s Shandong Boyuan Phar Shandong Boyuan Pharmaceutica; Co., Ltd, China issued by Food and Drug Administration China. The certificate is valid till 18-05-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of ADC for the import of Sacubitril/Valsartan (2.5 Kg, dated 08-07-2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

Sr. No.	Queries	Response submitted
1.	It shall justify the dissolution specification NLT 80%(Q) after 45 minutes, and using USP basket apparatus(I) at 75 rpm, since the USFDA review document of the innovator product specify dissolution specification i.e. NLT (Q) after 25 minutes using USP basket apparatus(II) at 50 rpm	FDA dissolution test Method applied on the product  Drug Name | Dosage Form | USP Apparatus | Speed (RPMs) Sacubitril/Valsartan | Tablet | I (Basket) | 75 Medium | Volume (mL) | Recommended Sampling Times (minutes) Phosphate Buffer, pH 6.8[degassed] | 900 | 10, 15, 20, 30 and 45
2.	Valid GMP certificate of API Manufacturer is required.	The firm has submitted GMP certificate for M/s Shandong Boyuan Phar Shandong Boyuan Pharmaceutical; Co., Ltd, China issued by Food and Drug Administration China. The certificate is valid till **18-05-2023**
3.	You have submitted only 3 month real and accelerated time stability data	Stability Data of 6th month was submitted
4.	Whether the reference standard exist as co-crystal complex sacubitril/valsartan or both are separate, provide COA of reference standard. Need detail of reference standard used for the performance of identification tests by comparing the IR spectra of the API shall be submitted	The working standard was provided by the supplier in Co-crystals complex sacubitril/Valsartan. The peaks of both the APIs were identified, by injecting pure USP Valsartan primary standard in to the chromatogram the retention time is 7.0 minute (chromatogram attached for reference) and also in LCZ 696 compound we have a peak on the same retention time which shows that this first peak is of valsartan, while the second peak is for sacubitril.

Decision: Registration Board approved the applications of Curin 97mg/103mg Tablet, Curin 49mg/51mg Tablet & Curin 24mg/26mg Tablet with Innovator's specifications.

- **Registration Board further decided that registration letter will be issued after submission of dissolution studies of three batches of each strength as per recommendations of US FDA at next time point of long term stability studies.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Miscellaneous Case

Case No. 01: Request of M/s Al-Habib Agencies for registration of applied poultry products (imported).

M/s Al-Habib Agencies, Rawalpindi vide its letter dated 24-08-2022 has requested for registration of applied poultry products for import from Vietnam. The request of the firm is placed below:

Dear Sir,

We, M/s. AL-HABIB AGENCIES is leading marketing company for the supply of Poultry & Livestock Medicine in Pakistan.

Unfortunately, in current circumstance of Flood in our Country, Viral Disease & Infections in Poultry & Livestock is increasing on Serious Alarming Level. Standard requirement and procedure for

registration of DRAP may be challenge to fulfil the need of such drugs in the country at this distasting situation.

M/s. AL-HABIB AGENCIES had applied for the registration of (15) imported products from Vietnam according to the criteria and mechanism for registration obtained by Drug Regulatory Authority of Pakistan (DRAP). These (15) applied products can easily control & counter against these life threatening diseases (Product details enclosed).

We are requesting that our application may kindly be consider and register our applied imported products so that we can help our farmers to protect their Livestock from Lumpy Skin Disease. We make sure to make immediate availability of applied products in our local market. We ensure that safe, effective and quality drug products will be made available to the citizen on immediate basis.

The list of the products for which firm has requested is as under:

Importer: M/s Al-Habib Agencies. Flat # 11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi

MA Holder Abroad: M/s HT Pharma Veterinary Import Export Liability Company. 69 Hung Vuong, Thoi Binh Ward, Ninh kieu District, Can Tho City, Vietnam

Sr. No	Product Name	R & I date in DRAP	Composition
1.	Pro Aminovit Injection	23-11-2021	Each ml Contains: Dextrose (Glucose)...50mg Calcium Chloride...2mg Potassium Chloride...2mg Magnesium Sulphate...2mg Sodium Acetate...7.5mg L-Histidine Hcl...0.02mg DL-Methionine...0.525mg L-Tryptophan...0.175mg L-Cysteine Hcl...0.02mg L-Threonine...0.35mg L-Isoleucine...0.525mg L-Arginine Hcl...1.425mg L-Phenylalanine...0.35mg L-Valine...0.525mg L-Lysine...0.525mg L-Leucine...0.6mg Monosodium Glutamate...0.08mg Riboflavin...0.05mg D-Panthenol...0.1mg Pyridoxine Hcl...0.1mg Nicotinamide...3mg Thiamine Hcl...0.1mg
2.	Flofenicol 20% Oral Solution	23-11-2021	Each 100ml Contains: Florfenicol…20gm
3.	Tilmicosin Oral Solution	23-11-2021	Each ml Contains: Tilmicosin Phosphate …… 250mg
4.	Flunixin 5% Injection	23-11-2021	Each ml Contains: Flunixin Meglumine…50mg
5.	Enrofloxacin 10% Oral Solution	23-11-2021	Each 100ml Contains: Enrofloxacin…10gm Colistin Sulphate…50MIU
6.	Para Plus Oral Powder	23-11-2021	Each 100gm Contains: Paracetamol…20gm Vitamin C…5gm Potassium Carbonate…12.5gm Sodium Bicarbonate…12.5gm Vitamin E…12.5gm
7.	Pollo-CRD Plus Oral Powder	23-11-2021	Each 1000gm Contains: Tylosin Tartrate…100gm Doxycycline Hcl…200gm Colistin Sulphate…450MIU

			Bromhexine Hcl…5gm Streptomycin Sulphate…36gm
8.	Pro ZSB Plus Powder	23-11-2021	Each 1000gm Contains: Procaine Penicillin…12gm Streptomycin Sulphate…36gm Zinc Bacitracin…52gm
9.	Pro-CRD Complex 30/20 WSP	23-11-2021	Each 100gm Contains: Tylosin Tartrate…200gm Doxycycline Hcl…400gm Colistin Sulphate…1000MIU Bromhexine Hcl…10gm
10.	Pro-Lamox-C WSP	23-11-2021	Each 100gm Contains: Amoxicillin Trihydrate…20gm Colistin Sulphate…50MIU
11.	Pro-Liso 4.4% Feed Premix Powder	23-11-2021	Each 100gm Contains: Lincomycin HCl…4.4gm
12.	Super Lamox-70% WSP	23-11-2021	Each 1000gm Contains: Amoxicillin Trihydrate…700gm
13.	Supet T.D Man-70% WSP	23-11-2021	Each 100gm Powder Contains: Doxycycline Hyclate Eq. to 800gm of Doxycycline…923.32gm
14.	Pro-Timi C		
15.	Pro-Cefo Injection	23-11-2021	Each ml Contains: Ceftiofur as Hcl…50mg

Decision: Registration Board considering the fact that generic products are available for the formulations requested by firm for priority consideration hence Board decided to consider the above referred applications on their turn.

Case No.01. Requests for Procurement of Controlled Drug Substance for Trial/ Development & Stability Purposes.

M/s Aspin Pharma (Pvt) Ltd. Plot No.10 & 25 Sector 20 Korangi Industrial Area Karachi has informed that OBS Group has entered into an agreement to acquire certain pharmaceutical brands currently being marketed by Pfizer Pakistan Limited. Amongst the brands being acquired, Xanax (Alprazolam) is a controlled product. Its existing commercial quota is expiring in May 2023, after which Pfizer will discontinue its manufacturing and Aspin Pharma Pvt. Ltd., will be responsible for manufacturing this product subject to the transfer of marketing authorization and approval of the commercial quota. Considering the stringent timelines, M/s Aspin is making efforts to expedite the process for the commencement of manufacturing of Xanax to prevent product shortages. Moreover, to ensure readiness to manufacture this drug M/s Aspin has submitted the psychotropic/ Narcotic section layout approval request to DRAP on 02-09-2022 which is currently under review.

In this regard, M/s Aspin has requested for permission to purchase controlled substance "Alprazolam" for trial, development and stability determination of following products. In this regard, the firm has also submitted fee of Rs.7500 per product. Detail is as under:

S. No.	Product Name/ Controlled Drug Substance/ Fee detail	Quantity Required for trial/ stability batches	Source
1	Aspinax Tablet (Alprazolam) ……..0.25mg (Deposit Slip #7494112315)	10 g	**Exporter:** M/s Pfizer Wyeth Holding LLC Address: 235 E, 42nd ST, New York NY 11017, USA. **Manufacturer:** M/s Pharmacia & Upjohn Company LLC Address: 7000 Portage Road Kalamazoo Michigan 4900.
	Aspinax Tablet (Alprazolam) ….....0.50mg (Deposit Slip #6559126203)	20 g	
	Aspinax Tablet (Alprazolam) ……1mg (Deposit Slip #3984010340)	40 g	
	Aspinax XR Tablet (Alprazolam)…0.50mg (Deposit Slip #642931803304)	20 g	
	Aspinax XR Tablet (Alprazolam) …1mg (Deposit Slip #836173752)	40 g	
	Aspinax XR Tablet (Alprazolam) … 2mg (Deposit Slip #67004747292)	80 g	
	Alprazolam (For QC Testing)	25 g	
Total		**235g**	
2	Alprazolam Working Standard	500 mg	
3	USP Alprazolam RS	200 mg (1Vial)	USP
4	USP Alprazolam Related Compound A RS	30 mg (1Vial)	
5	USP 2-Amino-5-chlorobenzophenone RS	25 mg (1Vial)	
6	USP Chlordiazepoxide Related Compound A RS	25 mg (1Vial)	
7	USP Nordazepam RS	50 mg (1Vial)	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S. No.	Product	API	Quantity Required per Tablet (mg)	No. of Packs / Batch	No. of batches	Quantity Required for trial/ stability batches		
					Trial + Stability	For Formulation Development	For QC testing & Retention	Total
1	Aspinax Tablet 0.25 mg	Alprazolam	0.25	Batch Size for trial batch 1 (5000 Tablets)	Trial Batches (2)+ Stability Batches (3)	g	g	g
				Batch Size for trial batch 2 (5000 Tablets)		10.0	25.0	35.0
				Batch Size for stability batch 1 (10000 Tablets)			Chemical Testing : 15 Retention Sample : 10	
				Batch Size for stability batch 2 (10000 Tablets)				
				Batch Size for stability batch 3 (10000 Tablets)				

S. No.	Product	API	Quantity Required per Tablet (mg)	No. of Packs / Batch	No. of batches	Quantity Required for trial/ stability batches		
					Trial + Stability	For Formulation Development	For QC testing & Retention	Total
2	Aspinax Tablet 0.50 mg	Alprazolam	0.5	Batch Size for trial batch 1 (5000 Tablets)	Trial Batches (2)+ Stability Batches (3)	g	g	g
				Batch Size for trial batch 2 (5000 Tablets)		20.0	N/A	20.0
				Batch Size for stability batch 1 (10000 Tablets)			same lot will be use	
				Batch Size for stability batch 2 (10000 Tablets)				
				Batch Size for stability batch 3 (10000 Tablets)				

S. No.	Product	API	Quantity Required per Tablet (mg)	No. of Packs / Batch	No. of batches	Quantity Required for trial/ stability batches		
					Trial + Stability	For Formulation Development	For QC testing & Retention	Total
3	Aspinax Tablet 1 mg	Alprazolam	1	Batch Size for trial batch 1 (5000 Tablets)	Trial Batches (2)+ Stability Batches (3)	g	g	g
				Batch Size for trial batch 2 (5000 Tablets)		40.0	N/A	40.0
				Batch Size for stability batch 1 (10000 Tablets)			same lot will be use	
				Batch Size for stability batch 2 (10000 Tablets)				
				Batch Size for stability batch 3 (10000 Tablets)				

S. No.	Product	API	Quantity Required per Tablet (mg)	No. of Packs / Batch	No. of batches	Quantity Required for trial/ stability batches		
					Trial + Stability	For Formulation Development	For QC testing & Retention	Total
4	Aspinax XR Tablet 0.50 mg	Alprazolam	0.50	Batch Size for trial batch 1 (5000 Tablets)	Trial Batches (2)+ Stability Batches (3)	g	g	g
				Batch Size for trial batch 2 (5000 Tablets)		20.0	N/A	20.0
				Batch Size for stability batch 1 (10000 Tablets)			Same lot will be used	
				Batch Size for stability batch 2 (10000 Tablets)				
				Batch Size for stability batch 3 (10000 Tablets)				

S. No.	Product	API	Quantity Required per Tablet (mg)	No. of Packs / Batch	No. of batches	Quantity Required for trial/ stability batches		
					Trial + Stability	For Formulation Development	For QC testing & Retention	Total
5	Aspinax XR Tablet 1 mg	Alprazolam	1	Batch Size for trial batch 1 (5000 Tablets)	Trial Batches (2)+ Stability Batches (3)	g	g	g
				Batch Size for trial batch 2 (5000 Tablets)		40.0	N/A	40.0
				Batch Size for stability batch 1 (10000 Tablets)			same lot will be use	
				Batch Size for stability batch 2 (10000 Tablets)				
				Batch Size for stability batch 3 (10000 Tablets)				

S. No.	Product	API	Quantity Required per Tablet (mg)	No. of Packs / Batch	No. of batches	Quantity Required for trial/ stability batches		
					Trial + Stability	For Formulation Development	For QC testing & Retention	Total
6	Aspinax XR Tablet 2 mg	Alprazolam	2	Batch Size for trial batch 1 (5000 Tablets)	Trial Batches (2)+ Stability Batches (3)	g	g	g
				Batch Size for trial batch 2 (5000 Tablets)		80.0	N/A	80.0
				Batch Size for stability batch 1 (10000 Tablets)			same lot will be use	
				Batch Size for stability batch 2 (10000 Tablets)				
				Batch Size for stability batch 3 (10000 Tablets)				

In this context, the Board is further informed that M/s AGP Limited B-23-C, S.I.T.E., Karachi (DML No.000348) also submitted an application vide letter No. RA/DRAP/0147/2022 received dated 14-09-2022 for permission to purchase "Alprazolam" for product development on same grounds i.e., acquiring "Xanax" from M/s Pfizer Pakistan Limited, however, the firm vide their letter No. RA/DRAP/0149/2022 received dated 16-09-2022 informed regarding withdrawal of their initial application.

Decision: **Registration Board approved the allocation of controlled drug substances i.e. Alprazolam for trial, development & stability batches of above mentioned products. The Board advised the firm to maintain records of used substances and waste materials having above APIs will be destroyed after approval of Controlled Drug Division, DRAP. The Board further decided that Marketing Authorization to M/s Aspin Pharma (Pvt) Ltd. Plot No.10 & 25 Sector 20 Korangi Industrial Area Karachi shall be granted as per applicable policy regarding Psychotropic / Narcotic sections.**

Case No.02: Change in Registration status of Products from M/s OBS Pakistan (Pvt) Ltd., Karachi to M/S Aspin Pharma (Pvt.) Ltd. Karachi

Registration Board in its 317th meeting held on 16-17th May 2022 deferred following products due to the reasons mentioned in the last column below:

S.No	Reg.No	Name of the Product	Decision of Registration Board in 317th meeting
1.	081780	Anvol 2.5 mg Tablet Each tablet contains: Nebivolol (as HCl) … 2.5 mg (Manufacturer's Specification)	Registration Board deferred the case for submission of justification regarding un-even trends of dissolution profile of both the products i.e., Anvol Tablet 5 mg & 2.5 mg
2.	081069	Anvol 5 mg Tablet Each tablet contains: Nebivolol (as HCl) … 5 mg (Manufacturer's Specification)	---as above----

Now the firm has submitted their reply vide Diary Number 21691 dated 01 August 2022. The firm has submitted as below:

"In this regard, it is stated that; As per Dissolution profile guidelines of US FDA (enclosed herewith, pls. refer to Page 11, Section V), for comparison of dissolution, Dissimilarity factor (f1) and Similarity factor (f2) are calculated for different buffers at different time points and the f1 should be less than 15 while f2 should be greater than 50."

"In CDP of our products both f1 and f2 are within limits of US FDA guidelines and hence considered comparable for dissolution of Anvol 2.5mg & 5mg in comparison with its innovator product."

Decision: Registration Board deferred the case for further deliberation.

Registration-II Section

Case No.01 Registration for the drug(s) of M/s. Allmed (Private) Limited. Lahore.

Registration Board in 237th meeting considered the products of M/s. Allmed (Private) Limited Lahore. as per detailed below:-

S.No	Name of the drugs with composition	Pack Size	Proposed Price	Date of Submission	Remarks
1.	Isoflo Oral Solution Each 100ml contains:- Isoflurane…....100ml (Anesthesia)	100ml	As per SRO	10-11-2011 Fee.8000 11-10-2012 Fee.12000 Fast track fee submission Fee.40000	USFDA approved formulation is intended for inhalation route *Firm has clarified that applied formulation is as per reference product approved by USFDA with strength Isoflurane 99.9%* ***Also corrected brand name as Isoflo Solution***
2.	Sevoflo Solution Each ml contains:- Sevoflurane.....250ml (anesthesia)	250ml	-do-	10-11-2011 Fee.8000 11-10-2012 Fee.12000 Fast track fee submission Fee.40000	USFDA approved formulation is intended for inhalation route *Firm has clarified that applied formulation is as per reference product approved by USFDA with strength sevoflurane 100%*

Firm has submitted following documents:-

i. Application for this purpose.
ii. Copy of GMP conducted on 12.11.2018 (panel recommends DML renewal)
iii. Evidence of section (inhalants) approval by CLB not provided by the firm

Registration Board in its 287th meeting decided to confirm manufacturing facility for above mentioned formulations from Licensing division.

Accordingly Licensing Division was requested to confirmed the manufacturing facility of the above said product. Licensing Division has forwarded a letter of concerned FID which states that;

> "The representative of the firm informed that they will be manufacturing these products in syrup section (General) (Already Approved). However, a vessel in syrup manufacturing section was dedicated for these anesthetic inhalants. A separate syrup filling machine was also installed in a separate room for filling of these inhalant anesthetics. The filling machine was covered to avoid the accumulation of fumes in the room. The room had HVAC facility with separate AHU for this area. For the purpose of testing of these solutions, the firm had purchased GC apparatus of Agilent company."

Decision of 295th Meeting:

> Registration Board rejected the application as firm does not have approved section for manufacturing of anesthetic inhalants.

Accordingly, above decision of the Board was communicated to the firm vide letter No. 5-3/2020-Reg-II (M-295) dated 01-06-2022.

Firm has submitted appeal before Appellate Board against above decision of Registration Board and decision of Appellate Board is as under;

> **The Board after hearing the arguments, perusal of the record and getting the update about the availability of approved section by the Central Licensing Board decided to remand back the case to Registration Board for re-consideration of already decided applications in its next meeting.**

Now firm has requested to change fill volume of Isoflo Solution from 100ml to 250ml with submission of fee of Rs.30,000/- and submitted justification as under;

i. All the private and public institutions prefer / demand 250ml volume over 100ml due to convenience in usage and Patient compliance.
ii. Further 250ml fill volume is also approved by reference regulatory authority.

Firm has also submitted following;

i. Form-5 of Sevoflo Solution along with photocopy of fee challan of Rs.8000/-, Rs.12,000/- and Rs.40,000/-
ii. Revised Form-5 of Isoflo Solution along with photocopy of fee challan of Rs.8000/-, Rs.12,000/- and Rs.40,000/-
iii. Section approval of Liquid Solution for Inhalation (General) Section.
iv. GMP Certificate issued based upon evaluation conducted dated 11-06-2021.

Decision:

a. Registration Board approved the registration of above products in the name of M/s. Allmed (Private) Limited. Lahore as per following details:

i. Isoflo Solution
Each Vial contains:-
Isoflurane…....250ml

ii. Sevoflo Solution
Each Vial contains:-
Sevoflurane.....250ml

b. Fee shall be verified as per decision of 285th meeting of Registration Board.

c. Registration Board further decided that firm shall perform pharmaceutical equivalence study against the innovator drug product before commercialization of products.

Case No.02 Correction in Minutes of Registration Board Meetings.

i. M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore

Registration Board in its 295th meeting approved following product of M/s Aptcure Pvt Ltd; 8-Pharma City, 30 km Multan Road, Lahore. Registration letter was not issued as there is some typo error in strength of formulation. Details are as under;

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition	Remarks
1.	Laget 200mg Capsule Each Capsule Contains: **Fenofibrate…..20mg** USP	Laget 200mg Capsule Each Capsule Contains: **Fenofibrate…..200mg** USP	Registration letter not yet issued

Firm has submitted receiving of registration application which reveals that stance of the firm is justified.

Decision: **Registration Board decided to approve the correction in above product as per following details.**

"Laget 200mg Capsule
Each Capsule Contains:
Fenofibrate…..200mg"

ii. M/s Carer Pharmaceuticals Plot # 27, Main Road, Rawat Industrial Estate Rawat.

Registration Board in its 317th meeting approved following product of M/s Carer Pharmaceuticals Plot # 27, Main Road, Rawat Industrial Estate Rawat by way of contract manufacturing from M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad. Registration letter was not issued as there is some typo error in strength of formulation. Details are as under;

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition	Remarks
1.	BRIAR 200mg/5ml suspension Each 5ml of reconstituted suspension contains: **Cefixime (as trihydrate)……100mg** USP specs	BRIAR 200mg/5ml suspension Each 5ml of reconstituted suspension contains: **Cefixime (as trihydrate)……200mg** USP specs	Registration letter not yet issued

Firm has submitted receiving of registration application which reveals that stance of the firm is justified.

Decision: **Registration Board decided to approve the correction in above product with following details.**

"BRIAR 200mg/5ml suspension
Each 5ml of reconstituted suspension contains:
Cefixime (as trihydrate)……200mg"

Case No.03: M/s. Medisave Pharmaceuticals Plot No: 578-579 Sundar Industrial Estate, Sundar Raiwind Road, Lahore

Registration Board in 312th meeting approved following product of M/s. Medisave Pharmaceuticals Plot No: 578-579 Sundar Industrial Estate, Sundar Raiwind Road, Lahore. Deatil is as under;

Sr. No.	Name of Approved Drug(s) & Composition	Demanded Pack size & Price	Decision of 312th meeting
1.	Amisave Injection 250mg /2ml Each ampoule 2ml contains:- Amikacin sulphate ….. 250mg USP	2ml, As per SRO	**Approved.** **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of equivalency factor in composition as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021**

While issuance of registration letter, it was transpired that Amikacin 250mg/2ml is not available in any of reference regulatory authorities while RRA approved formulation is Amikacin 250mg/ml.

Now firm has submitted fee of Rs.30,000/- for correction for formulation in line with RRA as

"Amisave Injection 250mg /ml
Each ml ampoule contains:
Amikacin sulphate eq. to Amikacin….250mg"

Decision: **Registration Board decided to approve the change in formulation of above product with following details.**

"Amisave Injection 250mg /ml
Each ml ampoule contains:
Amikacin sulphate eq. to Amikacin….250mg"

Case No.04: M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore.

Registration Board in 297th meeting approved following product of Registration Board in 312th meeting approved following product of M/s. Medisave Pharmaceuticals Plot No: 578-579 Sundar Industrial Estate, Sundar Raiwind Road, Lahore. Deatil is as under;

Sr. No.	Name of Approved Drug(s) & Composition	Demanded Pack size & Price	Decision of 297th meeting

1.	Norline 1mg/ml Injection Each ml Contains: Noradrenaline Acid Tartrate (eq to Noradrenaline 1mg/ml)…….2mg BP	2ml x5's , 2ml x10's: As per SRO	**Approved**

While issuance of registration letter, it was transpired that mee-too of Noradrenaline injection with fill volume of 2ml is not available.

Now firm has submitted fee of Rs.30,000/- for correction for fill volume from 2ml to 4ml.

Accordingly, label claim has also been standardized as per reference MHRA as

"Norline 1mg/ml Concentrate for Solution for Infusion (4ml)
Each ml Contains:
Noradrenaline Tartrate 2mg eq. to Noradrenaline …… 1mg"

Decision: **Registration Board decided to approve the change in fill volume of above product with following details.**

"Norline 1mg/ml Concentrate for Solution for Infusion (4ml)
Each ml Contains:
Noradrenaline Tartrate 2mg eq. to Noradrenaline …… 1mg"

Export Facilitation Desk

Case No.01: Registration of Drug (s) of M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI) Rawat, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-9/2004-Lic dated 04-07/2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 09-03-2020
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Sodium Adenosine Triphosphate Injection 1% Each 1ml contains: ATP disodium salt (adenosine triphosphate disodium salt).....1%	Purchase order from Tajikistan	Dy. No. 8187 (26.08.2022) Rs.75,000/- (25.08.2022) Adenosine 3mg/ml is approved in USFDA ATP 10mg/ml injection is available in Ukarine
2.	Nicotinic Acid Injection 1% Each ampoule contains: Nicotinic Acid.....1%	Purchase order from Tajikistan	Dy. No. 8188 (26.08.2022) Rs.75,000/- (25.08.2022) NICOTINIC ACID Tablet is approved in USFDA as 500mg to 2000mg extended release form
3.	Levomecytin Tablet Each tablet contains: Chloramphenicol.....500mg	Purchase order from Tajikistan	Dy. No. 8189 (26.08.2022) Rs.75,000/- (25.08.2022) Chloramphenicol 500mg capsule is included in National Drug Formulary Philippine Chloramphenicol 250mg tablet is approved in USFDA

Decision: Registration Board considered the case and decided as follows:

a) **Approved products at Sr No 1 and 3 for export purpose. Since applied formulations are neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.**
b) **Deferred product at Sr No 2 for confirmation of availability of Nicotinic Acid injection internationally and its intended use in importing country.**

Case No.02: Registration of Drug (s) of M/s Bio-Labs (Pvt.) Ltd, Plot No. 145, Industrial Triangle Kahuta Road Islamabad, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents

Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-12/89-Lic dated 23-07/2012
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 03-08-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Morbis Infusion 42mg/ml (100ml) Each ml contains: L-Arginine HCl.....42mg	Purchase order from Uzbekistan	Dy. No. 8215 (02.09.2022) Rs.75,000/- (01.09.2022) **Remarks** L-Arginine HCl 10% injection is approved in USFDA

Decision: Registration Board approved above mentioned product of M/s Bio-Labs (Pvt.) Ltd, Plot No. 145, Industrial Triangle Kahuta Road Islamabad, since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product

Case No.03: Registration of Drug (s) of M/s MTI Medical (Pvt.) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Lahore, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-39/2005-Lic dated 11-04/2017
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 09-02-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Gluto Lyophilized Injection 2500mg/vial Each lyophilized vial contains: L-Glutathione.....2500mg	Purchase order from Kazakhstan	Dy. No. 8244 (15.09.2022) Rs.75,000/- (08.09.2022) Glutathione 600mg is available in AIFA rather than L-Glutathione

Decision: Registration Board deferred the above mentioned product for approval / regulatory status of applied formulation in importing country.

Case No.03: Registration of Drug (s) of M/s Pacific Pharmaceuticals Ltd, 30-Km, Multan Road, Lahore, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents

Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Inspection report renewal of DML dated 13-04/2017
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 14-09-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Aspirin EC 80mg Tablets Each Enteric coated tablet contains: Aspirin.....80mg	Purchase order from Philippines	Dy. No. 8255 (16.09.2022) Rs.75,000/- (22.08.2022)

Decision: Registration Board approved above mentioned product of M/s Pacific Pharmaceuticals Ltd, 30-Km, Multan Road, Lahore since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product

Deferred CASE of 85th PRVC

Case No.04: Registration of Drug (s) of M/s. Danas Pharmaceuticals (Pvt.)Ltd, 312, Industrial Triangle Kahuta Road, Islamabad, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages 40-68/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided (Page-71/C). Approval of relevant section verified from letter No. F 1-44/2003-Lic dated 15-06-2011 (Page 69/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated **30-10-2017** (Page 72-75 -/C).**The firm has also submit request for renewal of DML /cGMP inspection at Page 70-75/C**
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages.76/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No.(EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Oxydan 10IU/ml Injection Each Ampoule (1ml) contains: Oxytocin.....10IU	Oxydan Injection by M/s Amros	Dy. No. 8192/22 (29.08.2022) Rs.30,000/- (01.08.2022)
Remarks: We hereby hormone categorically undartake that we will produce above said product in our dedicated Steroidal Section facility. We hereby solemnly affirm and declared that we will not produce any steroidal product during the manufacturing period of our applied product Oxydan 10IU Injection (Oxytocin) in that area			

Decision 85 PRVC : The Committee considered the case and referred it to Registration Board.

Decision: Registration Board deferred the above mentioned product for section approval/manufacturing facility of hormonal (non-steroidal) injectable section.

Case No:01 Change of formulation of registered product of M/s Werrick Pharmaceuticals, Plot # 216-217, Sector I-10/3 Industrial Area ,Islamabad

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Werrick Pharmaceuticals, Plot # 216-217, Sector I-10/3 Industrial Area ,Islamabad
	Name, address of Manufacturing site.	M/s Werrick Pharmaceuticals, Plot # 216-217, Sector I-10/3 Industrial Area , Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26523 dated: 24/09/2021
	Details of fee submitted	PKR 30,000/-: dated: 17/09/2021
	The proposed proprietary name / brand name	Peptiban Dry Suspension 40mg/5ml **Reg No. 025037** Renewal submitted on 04.07.2019 (**within due date)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml (After reconstitution) Contains: Famotidine…….. 40mg
	Pharmaceutical form of applied drug	Dry Suspension
	Pharmacotherapeutic Group of (API)	Histamine -2 (H_2) Receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	60 ml suspension after reconstitution
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pepcid for Oral dry suspension USFDA Approved.
	For generic drugs (me-too status)	Sofem dry suspension 40mg by M/s Roryan Pharmaceuticals Reg. No. 082573
	GMP status of the Finished product manufacturer	Last GMP conducted on on 09/11/2018
	Name and address of API manufacturer.	M/s Vaasavaa Pharmaceuticals(Pvt) Ltd. India Plot # C-216 & 217 Maharashtra- 413 255, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Famotidine is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related compound D,C, F, B, E and Famotidine cyanomide & Famotidine amidine related compound, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions:

		Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (FM-IV/05/001, FM-IV/05/002, FM-IV/05/003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (Pharmaceutical equivalence for assay and pH) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the competitor Product Sofem dry suspension 40mg per 5ml by Roryan Pharma by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Vaasavaa Pharmaceuticals(Pvt) Ltd. India Plot# C-216 & 217 Maharashtra- 413 255, India.		
API Lot No.	FAM-0120013		
Description of Pack (Container closure system)	Amber colored Bottle with white pilfer proof cap (60ml suspension after reconstitution in 90ml bottle)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12, 18, 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	200 Bottles	200 Bottles	200 Bottles
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	25-02-2021	26-02-2021	01-03-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 6100728 issued by FDA (Maharashtra State) valid till 19/07/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice No. EP-20-21/089 Dated 13-06-2020 wherein the permission to import Famotidine USP for the purpose of test/ analysis / stability studies and manufacturing is granted. Copy of letter No. 2110/2020-/AD (I&E) dated 17-08-2020. Batch No. FAM-0120013
4.	Data of stability batches will be supported by attested respective documents like chromatograms,	Submitted

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

Remarks of Evaluator:

- Firm applied for change of already registered formulation i.e Peptiban Suspension (Famotidine 10mg/5ml) Reg No. 025037 into Peptiban Dry Suspension (Famotidine 40mg/5ml) in line with USFDA approved formulation i.e Pepcid oral dry suspension (40mg/5ml)
- **Dry powder section (General) has not been approved by CLB.**
- **Last GMP conducted on 09/11/2018**
- **Volume of diluent for reconstitution is not been provided by firm along with justification (weight/ml calculation) with reference to innovator/reference product.**
- **Stability data of reconstituted suspension up to proposed shelf life is not provided by the firm**

Decision 313th meeting: Registration Board deferred the request of firm for following requirements:

a) Confirmation of updated GMP status
b) Submission of evidence for section approval i.e Dry powder section (General) by CLB
c) Submission of Volume of diluent for reconstitution along with justification (weight/ml calculation) with reference to innovator/reference product.
d) Submission of Stability data of reconstituted suspension up to proposed shelf life

Reply (dated 07.02.2022):

S.No	Observation	Reply	Remarks
1.	Confirmation of updated GMP status	Panel has been constituted dated 03.01.2022 however Inspection yet to be conducted	GMP status yet to be verified.
2.	Submission of evidence for section approval i.e Oral Dry powder section (General) by CLB	Panel has been constituted dated 03.01.2022 however Inspection yet to be conducted	Oral Dry powder section (General) not approved yet.
3.	Submission of Volume of diluent for reconstitution along with justification (weight/ml calculation) with reference to innovator/reference product.	Firm has submitted required volume of diluent for reconstitution i.e 40ml moreover weight/ml calculation has been justified against reference product i.e **Sofem Dry Suspension (Reg No 082573) by Roryan Pharmaceutical.**	Weight/ml quantity of applied formulation (1.17g/ml) found comparable to reference product (1.16g/ml)
4.	Submission of Stability data of reconstituted suspension up to proposed shelf life	Firm has submitted in use shelf life data of 3 batches as follows: **Batch No**. Trial no 01 Trial no. 02 Trial no. 03 **Batch size**: 200 bottles **Testing interval:** 0, 7th day, 14th day, 21st day and 30th day. **Parameters:** Physical appearance, taste, pH, Assay.	Complies ***Note for Guidance on in use stability testing of human medicinal products (EMA)*** ***WHO technical report series No 953.2009*** ***Stability testing of new Drug Substances and Products ICH Q1A(R2)***

		Date of initiation 22.11.2021	

Decision 316th meeting:

Registration Board deferred the request for following requirements:

a) Confirmation of updated GMP status
b) Submission of evidence for section approval i.e Dry powder section (General) by CLB

Updated status:

Firm has submitted following requirements:

a) Updated GMP inspection report dated 5th, 11th and 12th August 2022.
b) Evidence of section approval i.e Oral Dry Powder Suspension (General) based on DML Renewal Inspection report dated 5th, 11th and 12th August 2022.

Decision: Registration Board decided as follows:

a. **Acceded to request of M/s Werrick Pharmaceuticals, Plot # 216-217, Sector I-10/3 Industrial Area ,Islamabad for change of formulation of Peptiban Dry Suspension (Famotidine 10mg/5ml) Reg No. 025037 into Peptiban Dry Suspension (Famotidine 40mg/5ml) in line with USFDA approved formulation i.e Peptiban oral dry suspension (40mg/5ml).**
b. Manufacturer shall place first three production batches on real time stability studies throughout the proposed shelf life and on accelerated stability studies for six months.
c. Manufacturer will perform process validation of first three batches as per commitment submitted in registration application.
d. Firm shall perform concurrent stability (on commercial batches) of re-constituted drug product to ensure that quality of ready to use product will remain within accepted specification limits.
e. Reference will be send to Cost & pricing Division for MRP of new drug product.

Referred cases of 85th PRVC

Case No. 02 Applications of M/s Seraph pharmaceuticals, Kahuta road Islamabad for change of contract manufacturer from M/s Rotex pharma (Pvt) Ltd, Islamabad to M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP.

M/s Seraph Pharmaceuticals, Plot No 210, Industrial triangle Kahuta road Islamabad has submitted following application on Form 5F for change of contract manufacturer as follows:

Sr No	Reg No. / date of Reg.	Product name with composition	Existing contract manufacturer	Proposed contract manufacturer	Date of submission
1.	110932 29.12.2021	Empro 40mg Injection Each vial contains: Esomeprazole as sodium……40mg	M/s Rotex pharma (Pvt) Ltd, Plot No 206-207 Industrial triangle, kahuta road Islamabad	M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP	22.06.2022 DRAP (R&I) Rs 75,000/- dated 11.05.2022

Above mentioned formulations on Form 5F applications have already been approved by Registration Board in **312th meeting** at the same manufacturing site i.e. **M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP** as per following details:

Sr No	Reg. No.	Product name with composition	Applicant/manufacturer
1.	111031	Aegis 40mg injection Each vial contains: Esomeprazole as sodium……..40mg	M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP
Remarks:- Firm has submitted stability data of trial / lab scale batches. Registration Board in 312th Meeting decided that the permission for contract manufacturing is usually granted for the products which are already manufactured by the contract manufacturer, therefore, the Board decided that the permission for contract manufacturing shall be granted on the basis of stability study data of commercial batches			
***Decision 85 PRVC : The committees considered the case and referred to Registration Board*.**			

Decision: Registration Board deliberated the matter in detail and decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer. Hence

Registration Board approved instant case of change of contract manufacturing site of Empro 40mg Injection from M/s Rotex pharma (Pvt) Ltd, Plot No 206-207 Industrial triangle, kahuta road Islamabad to M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP.

Case No. 3 Applications of M/s. Hoover pharmaceuticals Lahore for change of contract manufacturer from M/s Mass Pharma(Pvt) Ltd Lahore to M/s Biogen Life Sciences 8Km Chakbeli Road, Rawat, RWP.

M/s Hoover pharmaceuticals Lahore has submitted following application on Form 5F for change of contract manufacturer as follows;

Sr No	Reg No. / date of Reg.	Product name with composition	Existing contract manufacturer	Proposed contract manufacturer	Date of submission
1.	099921 09.12.2019	Tretigen 20mg soft gelatin capsule Each soft gelatin capsule contains: Isotretinoin……..20mg	M/s Mass Pharma(Pvt) Ltd, 17 km Ferozepur Road, Lahore	M/s Biogen Life Sciences, 8Km 8KmChakbeli Road, Rawat, RWP	08.09.2021 DRAP (R&I) Rs 50,000/- dated 26.04.2021 Rs 25000/- dated 06/04/2022

Above mentioned formulations on Form 5F applications have already been approved by Registration Board in **312th Meeting** at the same manufacturing site i.e. **M/s Biogen Life Sciences,8Km Chakbeli Road, Rawat, RWP** as per following details:

Sr No	Reg. No.	Product name with composition	Applicant/manufacturer
1.	111034	Altrezam 20mg capsule Each soft gelatin capsule contains: Isotretinoin……..20mg	M/s Biogen Life Sciences 8Km Chakbeli Road, Rawat, RWP
Remarks:- Firm has submitted stability data of trial / lab scale batches. ***Registration Board in 312th Meeting decided that the permission for contract manufacturing is usually granted for the products which are already manufactured by the contract manufacturer, therefore, the Board decided that the permission for contract manufacturing shall be granted on the basis of stability study data of commercial batches***			
Decision 85 PRVC : The committees considered the case and referred to Registration Board.			

Decision: Keeping in view decision in case No.03, Registration Board approved change of contract manufacturing site of Tretigen 20mg soft gelatin capsule from M/s Mass Pharma(Pvt) Ltd, 17 km Ferozepur Road, Lahore to M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, Rawalpindi.

Case No. 04: Applications of M/s Biogen Pharma 8Km Chakbeli Road Rawat, Rwp for change of contract manufacturer from M/s Valor Pharmaceuticals 124/A, Industrial Area, Kahuta Road, Islamabad to M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP.

M/s Biogen Pharma 8Km Chakbeli Road Rawat, Rwp has submitted following application on Form 5F for change of contract manufacturer as follows;

Sr No	Reg No. /date of registration	Product name with composition	Existing contract manufacturer	Proposed contract manufacturer	Date of submission
2.	113104 22.07.2022	Isotone 20mg capsule Each soft gelatin capsule contains: Isotretinoin……..20mg	M/s Valor Pharmaceuticals 124/A, Industrial Area ,Kahuta Road, Islamabad	M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP.	05.08.2022 DRAP (R&I) Rs 75000/- dated 22.07.2022
3.	113103 22.07.2022	Isotone 10mg capsule Each soft gelatin capsule contains: Isotretinoin……..20mg			05.08.2022 DRAP (R&I) Rs 75000/- dated 22.07.2022

Above mentioned formulations on Form 5F applications have already been approved by Registration Board in **312th meeting** at the same manufacturing site i.e **M/s Biogen Life Sciences**, **8Km Chakbeli Road, Rawat, RWP** as per following details:

Sr No	Registration No.	Product name with composition	Applicant/manufacturer
1.	111034	Altrezam 20mg capsule Each soft gelatin capsule contains: Isotretinoin……..20mg	M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP.
2.	111033	Altrezam 10mg capsule Each soft gelatin capsule contains: Isotretinoin……..10mg	
Remarks:- Firm has submitted stability data of trial / lab scale batches. ***Registration Board in 312th Meeting decided that the permission for contract manufacturing is usually granted for the products which are already manufactured by the contract manufacturer, therefore, the Board decided that the permission for contract manufacturing shall be granted on the basis of stability study data of commercial batches***			
Decision 85 PRVC : The committees considered the case and referred to Registration Board.			

Decision: Keeping in view decision in Case No.03, Registration Board approved change of contract manufacturing site of Isotone 20mg capsule and Isotone 10mg capsule from M/s Valor Pharmaceuticals 124/A, Industrial Area ,Kahuta Road, Islamabad to M/s Biogen Life Sciences, 8Km Chakbeli Road, Rawat, RWP.

Case No. 05: Application for Extension of Shelf life of M/s Bayer Pakistan (Pvt) Ltd, Lahore.

a) Product name: Baycuten N cream (Reg No. 111897)
(Clotrimazole……1%w/w Dexamethasone 0.4%w/w)
Current shelf life: 2 years
Proposed shelf life: 3 years

Sr.#	Documents required (as per SOP M-283)	Information provided
1.	Application with required fee as per relevant SRO.	Date of application 31.03.2022 Dy No 8475(R&I) DRAP. Rs 10000/- deposited dated 25.03.2022
2.	Copy of registration letter and last renewal status	Reg No. 111897 dated 18th March,2022 Previously registered in the name of M/s Bayer Pakistan (Pvt) Ltd, Karachi, (Reg No 012639)
3.	Proposed shelf-life, justification & data of long-term stability testing (as per conditions of zone IV-A) including chromatograms for a minimum of 3 commercial scale batches or development scale batches as set by Registration Board in 276th meeting up to the proposed shelf-life.	**Accelerated studies** (Temp 40◦C±2◦C/ RH 75%±5%) Interval:0,3 and 6 months **Long term studies** (Temp 25◦C±2◦C /RH 60%±5%) **Interval**: 0,12,24 and 36 months **Study period**: Sep 2014-August 2017 **Testing parameters**: appearance, identification, pH. Degradation products, Assay **Reference: manufacturer specification** **Batch size**: 14,492 packs **Batch no**: KH02014, KH02015, KH02016 **Type of container:** Aluminum tubes
4.	□n undertaking that□□ • No change to the primary packaging type that is in direct contact with the FPP and to the recommended conditions of storage • No change in formulation and specification either of finished product, API and excipients etc.	Provided

	• In case both the above conditions are involved then manufacturer will submit complete requisite information as per procedure • In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.		
5.	**Remarks:**	Baycute-N is also approved in DIMDI (Germany) wherein approved shelf life is 3 years and storage is below or at 25◦C	

Firm has submitted documents as follows:

S. No	Document submitted	Remarks
1.	Stability protocol	Information provided about: stability study requirement, batch size, batch information, storage condition and testing interval, sampling plan, testing parameter and acceptance criteria,
2.	Stability data	Firm has submitted chromatograms, certificate of analysis and raw data sheet for each time interval along with stability data sheets
3.	Validation studies	Analytical method validation studies (specificity, accuracy, precision, linearity and LOD/LOQetc) has been performed

Remarks:

1) Testing frequency was 0,12,24 and 36 months, firm was of opinion that study was conducted in year 2014 at that time stability studies were not performed with such time interval i.e 0,3,6,9,12,18,24 however Baycute-N cream is well established product. Furthermore, firm has referred to

Annex 5 Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms as under:

For on-going studies, samples may be tested at 6-month intervals for the confirmation of the provisional shelf-life, or every 12 months for well-established products. Highly stable formulations may be tested after the first 12 months and then at the end of the shelf-life.

2) Firm performed studies at Temp 25◦C±2◦C /RH 60%±5%, firm submitted justification of not performing stability studies at Zone IV-A condition was as under:

Dexamethasone acetate content remain within specification limit after 36months storage at Temp 25◦C±2◦C /RH 60%±5% and 6 months storage at 40◦C±2◦C/ RH 75%±5% for all batches tested. Out of specification results for 2 of the batches tested (X001 and X002) were observed after 36months storage at Temp 30◦C±2◦C /RH 65%±5%, these results are covered by storage recommendation given for the finished product i.e "Do not store above 25◦C".

Decision 85 PRVC: ***The committee considered the case and referred it to Registration Board.***

Decision: **Registration Board considered the case and acceded to request of M/s Bayer Pakistan (Pvt) Ltd, Lahore for extension of shelf life of Baycuten N cream (Reg No. 111897) from 2 years to 3 years. Furthermore, firm was advised to ensure adherence to storage conditions throughout the supply process i.e storage and transportation.**

VETERINARY

Case No.01:- DEFERRED FOR DISCUSSION REGARDING REQUIREMENT FOR STEROIDAL MANUFACTURING FACILITY.

Registration Board in its 308th meeting deferred products for discussion regarding requirement for steroidal manufacturing facility of M/s. Vetz Pharmaceuticals (Pvt) Ltd., Kotri, Sindh of below mentioned drugs. The details are as under:-

1.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Progevet Injection (10ml)
	Composition	Each ml contains:- Progestrone (USP)……..25mg
	Diary No. Date of R& I & fee	Dy.No 14577 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	10ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Pregtone Injection of M/s. Star Labs. (Reg.#058711)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: Deferred for discussion regarding requirement for steroidal manufacturing facility.	
2.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Progevet Injection (50ml)
	Composition	Each ml contains:- Progestrone (USP)……..25mg
	Diary No. Date of R& I & fee	Dy.No 14578 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Harmones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	50ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Progestone Injection of M/s. Symans Pharmaceuticals (Pvt) Ltd., Lahore Registration No 063695
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: Deferred for discussion regarding requirement for steroidal manufacturing facility.	
3.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Cyclovet Injection (2ml)
	Composition	Each ml contains:- Cloprostenol Sodium 263mcg (B.P Vet) equivalent to Cloprostenol…….250mcg
	Diary No. Date of R& I & fee	Dy.No 14573 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Harmones
	Type of Form	Form-5

	Finished product Specifications	BP -Vet Specification
	Pack size & Demanded Price	2ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Cyclomate Injection (2.0 ml) M/s. Star Labs. Reg.No 012877
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: Deferred for discussion regarding requirement for steroidal manufacturing facility.	
4.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Cyclovet Injection (10ml)
	Composition	Each ml contains:- Cloprostenol Sodium 263mcg (B.P Vet) (equivalent to cloprostenol)…….250mcg
	Diary No. Date of R& I & fee	Dy.No 14574 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Harmones
	Type of Form	Form-5
	Finished product Specifications	BP -Vet Specification
	Pack size & Demanded Price	10ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Prostenol Injection (10.0ml) M/s. Selmore Labs. R.No. 029611
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: Deferred for discussion regarding requirement for steroidal manufacturing facility.	
5.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Lecivet Injection (2ml)
	Composition	Each ml contains:- Lecirelin (MS)…25mcg
	Diary No. Date of R& I & fee	Dy.No 14571 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	In house Specification
	Pack size & Demanded Price	2ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Serilin Injection (2.0, 10.0ml) M/s. Selmore Laboratories Registration No 071092
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: Deferred for discussion regarding requirement for steroidal manufacturing facility.	
6.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Lecivet Injection (10ml)
	Composition	Each ml contains:- Lecirelin (MS)……..25mcg
	Diary No. Date of R& I & fee	Dy.No 14572 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	In house Specification
	Pack size & Demanded Price	10ml/Decontrolled

	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Serilin Injection (2.0,10.0ml) M/s. Selmore Laboratories Registration No. 071092
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: Deferred for discussion regarding requirement for steroidal manufacturing facility.	
7.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Dinopovet Injection (5ml)
	Composition	Each ml contains:- Dinoprost (as trometamol) (EP)……5mg
	Diary No. Date of R& I & fee	Dy.No 14570 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	5ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Dprost Injection (5.0ml) M/s. Selmore Laboratories Registration No 088647
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: Deferred for discussion regarding requirement for steroidal manufacturing facility.	

(i) We are going to submit comprehensive reply on our 6 products namely (i) Progevet Injection 10ml (ii) Progevet Injection 20ml (iii) Cylovet Injection 2ml (iv) Cylovet Injection 10ml (v) Lecivet Injection 2ml (vi) Lecivet Injection 10ml & Dinopevet Injection 5ml. We desire the manufacturing facility for hormones.

(ii) Here we desire the condition in which production dedicated area clearly mentioned to hormone according to Schedule-B Drug Licensing and Registering and Advertising Rule in 1976. Keeping in this view we prepared separate and dedicated area's for hormone section. We apply 14 products for registration, so we request the Registration Board that all applied products in hormone section should be granted, if all products are being registered so the products containing oxytocin hormone should be suspended till we prepare new area and rest deferred products should be allotted because only two products does not meet expense of the area. We hope that above narrator will satisfy you.

The details of already registered hormone products are as under:-

S. No.	Reg. No.	Name of Drug(s) & Composition.	Packing	Maximum Retail Price.	Approved Shelf Life.
1.	109960	Buserovet Injection Each ml contains:- Buserelin Acetae…….0.0042mg equivalent to Buserelin…..0.004mg (As per Innovator's Specification)*	2.5ml	De-controlled	02 years
2.	109961	Buserovet Injection Each ml contains:- Buserelin Acetae..……...….0.0042mg (equivalent to Buserelin.....0.004mg (As per Innovator's Specification)*	5ml	De-controlled	02 years
3.	111468	Oxytovetz Injection Each ml contains:- Oxytocin (USP)……..10 IU (USP Specifications)	50ml	De-controlled	02 years

4.	111469	Oxytovetz Injection Each ml contains:- Oxytocin (USP)…..….10 IU (USP Specifications)	100ml	De-controlled	02 years
5.	111470	Oxytovetz Injection Each ml contains: Oxytocin (USP)……..10 IU (USP Specifications)	250ml	De-controlled	02 years
6.	111471	Oxytovetz Injection Each ml contains:- Oxytocin (USP)……..10 IU (USP Specifications)	500ml	De-controlled	02 years
7.	111472	Oxytovetz Injection Each ml contains:- Oxytocin (USP)……20 IU (USP Specifications)	100ml	De-controlled	02 years

Decision: Registration Board considered and deferred for further deliberation.

Import & Vet-II Section

HUMAN IMPORT

Case No.01:- Registration of Imported Drugs

M/s AGP Limited, B-23, C S.I.T.E, Karachi has submitted the applications dated 06th August 2021 of below mentioned four products on form-5F for registration to their name from M/s Galaxay Pharma (Private) Limited Karachi

Sr.#	Reg.#	Name of Product	Manufacturer & Product License Holder	Manufacturer & Product License Holder as per CoPP
1.	066122	Ostrodose Gel in Canister with Metering Pump	M/s Besins Manufacturing Belgium S.A., Belgium. Registered (Dated 28-10-2010, renewal dated 24-08-2020)	**Manufacturer: -** M/s Delpharm Drogenbos SA Address: Groot Bijgaardenstraat 128, Drogenbos, 1620, Belgium **Product License Holder: -** M/s Besins Healthcare Benelux S.A, Address: Avenue Louise 287-1050 Brussels, Belgium.
2.	066123	Ostrogel Gel in Tube		
3.	062214	Utrogestan 100mg Capsules (Initial Registered Dated 27-04-2010, renewal dated 10-03-2020)	Manufacturer:- M/s Cyndea Pharma, S.L., Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110 (Soria) Spain Product License Holder: - M/s Besins Healthcare Benelux 287, Avenue Louise 1050 Bruxelles (Belgium) Change of manufacturing site dated 18-05-2020	**Manufacturer: -** M/s Cyndea Pharma S.L. Address: Poligono Industrial Emiliano Revilla Sanz Avenida de Agreda, 31 Olvega 42110 (Soria), Spain **Product License Holder: -** M/s Besins Healthcare S.A, Address: Avenue Louise 287-1050 Brussels, Belgium
4.	059079	Utrogestan 200mg Capsule (Registered Dated 16-10-2009, renewal dated 25-03-2019)		

M/s AGP Limited submit following documents:

i. Application on form-5F along with fee Rs 150,000 for each product.
ii. M/s. AGP Limited, B-23 S.I.T.E, Karachi submit **termination letter** from M/s Besins Healthcare Benelux 287, Avenue Louise 1050 Bruxelles (Belgium) Dated 25th May 2021.

iii. M/s. AGP Limited, B-23 S.I.T.E, Karachi submitted **authorization letter** from M/s Besins Healthcare Benelux 287, Avenue Louise 1050 Bruxelles (Belgium) for above mentioned product.

Suit No. 2707 of 2021
M/s AGP Limited & Others Versus M/s Galaxy Pharma (Private) Limited & Others
In view of above facts and circumstances, allow the application under consideration as under:

I) That the defendant No.1, its officers, employees, agents and every person working through or under it, or on his behalf from representing or claiming themselves as partners, distributors, affiliates or representatives of plaintiff No.2 and is restrained from claiming any rights in the products, i.e.,
   a) Utrogestan 100 mg soft capsule
      (Micronized Progesterone 100mg)
      (For Oral or Vaginal use)
   b) Utrogestan 200 mg soft capsule
      (Micronized Progesterone 200mg)
      (For Oral or Vaginal use)
   c) Oestrogel Gel (in Tube)
      (Estradiol 0.6 mg/g)
   d) Oestrodose Gel
      (in Canister with metering pump)
      (Estradiol 0.6 mg/g)
   or utilizing the registration certificate of these products in any manner whatsoever.

II) As far as the importing of subject goods are concerned since it is an independent issue not arising out of the arguments, as raised, if otherwise prohibited, I am not inclined to pass any such order in this regard unless argued independently.

III) That the Drug Regulatory Authority within 15 days from the date of this order shall decide about the fate of registration of the above drugs in favour of defendant No.1 under the above facts and circumstances without asking for any NOC from defendant No.1 and submit report in this regard before this Court.

IV) In case they (Drugs Regulatory Authority) reaches to a conclusion that on account of severance of the contract, defendant No.1 is no more entitled to retain the registration of the aforesaid drugs and consequently cancel all such registrations, the application of the Besins Healthcare Distribution FZ-LLC and that of its principal be taken into consideration with immediate effect and an order be passed in this regard at the earliest with report to this Court.

Remarks:
The initial registration letter does not shows about the usage form of capsule but M/a AGP submit CoPP for both Oral and Vagianl Capsule for the product Utrogestan 100mg and 200mg Capsules.

Proceedings: -

Mr. Saif-ur-Rehman Director Marketing Business Development of M/s. Galaxy Pharma Karachi appeared before the Board and submitted interim order of Honourable High Court of Sindh at Karachi in HCA No.313 of 2022 dated 21.09.2022. He also provided a copy of termination of agreement issued by M/s. BESINS Health Care Benelux, Belgium wherein M/s. BESINS Health Care, Belgium has informed that M/s Besins Healthcare (Hong Kong) Ltd has terminated the distribution agreement with M/s Galaxy Pharma (Pvt Ltd) Karachi. M/s. BESINS Health Care Benelux, Belgium further added that they have a new distribution agreement with M/s. AGP limited B-23-C SITE, Karachi.
Registration Board raised query regarding product license holder of the products in question. Mr. Saif responded that Product License Holder of said product is M/s. BESINS Health Care Belgium. However, they made a contract with M/s Besins Healthcare (Hong Kong) Ltd. So, M/s Basin Healthcare Belgium has no right to cancel the distribution agreement made between M/s Galaxy Pharma Karachi and M/s Besins Healthcare (Hong Kong). The Board further inquired about the current status of agreement between Basin Healthcare Belgium and Besins Healthcare (Hong Kong) to which Mr Saif could not responded.

Registration Board after deliberation and keeping in view the above discussion decided to send an email to M/s Basin Healthcare Belgium, Product License Holder (as per CoPP) of the below mentioned products for following clarifications:

a) **Updated status of agreement between M/s Basin Healthcare, Belgium and M/s Besins Healthcare (Hong Kong) and to provide any documentary evidence if M/s Basin Heathcare Belgium has cancelled the authorization of M/s Basin Healthcare Hongkong.**
b) **Present authorized agent in Pakistan by the Product license holder i.e. M/s Basin Healthcare Belgium for following products:**
   a) **Utrogestan 100 mg soft capsule**
      (Micronized Progesterone 100mg)
      (For Oral or Vaginal use)
   b) **Utrogestan 200 mg soft capsule**
      (Micronized Progesterone 200mg)
      (For Oral or Vaginal use)
   c) **Oestrogel Gel (in Tube)**
      (Estradiol 0.6 mg/g)
   d) **Oestrodose Gel**
      (in Canister with metering pump)
      (Estradiol 0.6 mg/g)

Case No. 2. Guidance required regarding compliance with pharmacopeial specifications

Director Drug Testing Laboratory Faisalabad vide letter on subject "Guidelines Required regarding compliance with Pharmacopeial specifications" dated 06-09-2022, in which he has informed that the timeline given by the Registration Board has been ended on 26th April 2022. In the light of the decision of the Registration Board DTL Faisalabad requested the guidance on following:

Sr.#	DTL Faisalabad guidance requested points
1.	Manufacturers/ Registration holders of drug products that are still (May, 2022 onward) manufacturing their products as per Manufacturer's /Innovator's Specifications despite the availability of the monographs in Pharmacopoeia and are unable to provide DRAP's approval shall be Misbranded?
2.	If product specifications mentioned on the label are MS/Innovator's Specs and DRAP has not yet granted the approval though monograph is available in official pharmacopeias, which specifications would be opted to test/analyze the said product?
3.	In United States Pharmacopeia (USA), several tests are mentioned in dissolution test of various monographs and USP stated that except the test I, the Dissolution test number should be mentioned on the label of the product, If dissolution test no. is not printed on the label and manufacturer specify USP test 2 or test 3 in its method of analysis, on which dissolution test, the said product should be tested. And whether product would be declared misbranded or not.

Registration Board in its 317th meeting held on 16-17th May 2022 decided not to further extend timelines for compliance with pharmacopeial specifications.
Pharmaceuticals firms started to apply for specifications as per decision of Registration Board and PE&R division processed many of these applications and a number of applications are still under the process of evaluation and final approval.

Proceedings:
The Board was appraised that PE&R Division has already decided/disposed of cases applied for the change in specifications as per direction of the Board.

Decision: **Keeping in view above proceedings, Registration Board decided to advise the DTL Faisalabad to proceed in accordance with Drug Specification Rules 1978 for queries at S.No.1 and 2 while query at SNo.3 will be deliberated in the forthcoming meeting of Registration Board.**

Case No. 3. **<u>Eli Lilly Pakistan's request to make Labeling website Live with their current approved Leaflets/Prescribing Information</u>**

Eli Lilly Pakistan submitted application on 25-Aug-2022 for approval to make the website (www.mealabels.lilly.com) live and accessible to public/HCPs having their current approved Leaflets/Prescribing Information of their products:
E-Labeling is the dissemination of approved product information, via an electronic method (such as through a machine-readable QR code or URL) to the healthcare providers and patients.
With e-labeling, public/HCPs will have access to the most updated product information immediately after DRAP's approval/Notification.

In the below table, they further elaborated the benefits of e-labeling when it comes to patients, pharmacists and doctors:

Patient	Pharmacist	Doctor
❖ Access to the latest product information immediately after DRAP approval/Notification ❖ Product in the market will include the latest information	❖ Ability to access the locally approved product information without having to open the pack with the QR Code	❖ Providing a repository for doctors to reach local approved product information
Better readability and searchability of information		

Eli Lilly is implementing e-labeling across the Middle East countries through the addition of a QR code and a website URL to the product outer pack and physical leaflet.
Accordingly, once they got this 'website go live' approval, they will start notifying to DRAP artworks of their products by adding the QR codes and the website URL on the outer packs and leaflets.
Recently they have received approval to make their website Live from Lebanon and UAE Health Authorities.
They will not be eliminating the physical leaflet at this stage. The website will be updated right after new product information is approved by DRAP, allowing immediate implementation of label updates.
It is confirmed by the company that the website will only hold product information on the Pakistan pages that are already approved/Notified to DRAP.
Website layout also submitted with relevant pages to Pakistan.
Submitted for the recommendation of the Board for approval to make www.mealabels.lilly.com Labeling website Live with their current approved Leaflets/Prescribing Information.

Decision: Registration Board considered and deferred for further deliberation.

Case No. 4 <u>Request of M/S Bayer Pakistan (Pvt) Limited for Issuance of Formal Letter for Cancellation of Registration of Qlaira Tablet Due to Divestment of Licensed Facility</u>

M/s Bayer Pakistan (Pvt) Ltd, Korangi Industrial Area, Plot No. 23, Sector No.22, Karachi has submitted request for Issuance of Formal Letter for Cancellation of Registration of Qlaira Tablet Due to Divestment of Licensed Facility.
Details are as follows:

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative registered product
1.	Qlaira Tablet Each wallet (28 film coated tablets) contains: - Part I (2 dark yellow film coated tablets-Core) Estradiol valerate...3.0mg. Part II (5 medium red film-coated tablets-Core) Estradiol valerate...2.0mg. Dienogest....2.0 mg. Part III (17 light yellow film-coated tablets-Core) Estradiol valerate...2.0mg. Dienogest....3.0 mg. Part IV (2 dark red film-coated tablets-Core) Estradiol valerate...1.0mg. Part V (2 white film-coated tablets-Core)	088370	**Registration of Qlaira (oral contraceptive) is already not valid considering Licensed facility where Qlaira was registered *(i.e. C-21, S.I.T.E., Karachi, Pakistan)* had already been divested to Novartis in 2020-21 and transfer of Product (Qlaira) registration was not processed/requested since than by either Bayer Pakistan or Novartis. Further, Manufacturing site will not be able to produce and provide supplies for Pakistan.**	Famila, Desofam, (Zafa), Hytrade-C (Hygeia), Geogynon (Geofman Pharma)

	Placebo			

SOP Requirement	Firms Response
a) Application. b) Copy of registration letter. c) List of alternatives brands/ FPPs available in the country. d) An undertaking that: i. No case is pending at any forum / court of law regarding this product. ii. Provided information/ documents are true/ correct.	a. Application with a fee Rs.10,000/- b. Copy of registration letter (Reg. Letter date 28-02-2018). c. Above d. Provided by the firm.

Decision: Registration Board considered and referred the case to availability committee.

21	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.)Ltd**
	Details of Drug Sale License of the importer	**License No: 05-352-0065-016174D** **Address:** Ground Floor,6- Judicial Colony Phase-I (Ext.) Shahrah Nazaria e Pakistan, Lahore **Validity:** 06.02.2024. **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder & manufacturer	**Eskayef Pharmaceuticals Limited** **Registered Office**: 52 Motijheel Commercial Area, Dhaka 1000, Bangladesh. Operational Head Quarter: Plot 82, Road 14, Block B, Banani, Dhaka 1213, Bangladesh. Plant Address: 400 Squibb Road, Tongi Industrial Area, Tongi, Gazipur 1711, Bangladesh.
	Name of exporting country	**Bangladesh**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted the original, legalized CoPP certificate (No.DA/6-39/05/3733) dated 14-02-2022 issued by the Government of the people's republic of Bangladesh, Ministry of Health & Family Welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. **GMP:** Firm has submitted Legalized GMP certificate (Certificate No. DA/6-39/05/10970) issued by M/s Eskayef Pharmaceuticals Limited.
	Details of letter of authorization / sole agency agreement	Firm has submitted original letter of distribution certificate from Eskayef Pharmaceuticals Limited. Issue date 06-08-2022, Valid for 6 months from the date of issue
	Status of the applicant	☒ Importer
	Status of application	☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

	For imported products, specify one the these	☒ Finished Pharmaceutical product import
	Dy. No. and date of submission	Dy. No.24205: 26-08-2022
	Details of fee submitted	PKR 75,000/-: 04-08-2022
	The proposed proprietary name / brand name	**PAXOVIR Film Coated Tablets (2 strips Combipack)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each strip contains 2 light pink colour film coated tablets of Nirmatrelvir INN 150 mg each and 1 white color film coated tablet of Ritonavir USP 100 mg.)
	Pharmaceutical form of applied drug	Film Coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-retroviral
	Reference to Finished product specifications	Manufacturer's specs
	Proposed Pack size	2 strips (Combipack) Each strip contains 2 light pink colour film coated tablets of Nirmatrelvir INN 150 mg each and 1 white colour film coated tablet of Ritonavir USP 100 mg.
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	PAXLOVID 150 mg/100mg Film-Coated Tablets (UK)
	For generic drugs (me-too status)	PAXLOVID 150 mg/100mg Film-Coated Tablets of M/s Pfizer
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability the studies of the drug substance.
	Nirmatrelvir	
	Name, address of drug substance manufacturer	KAIFENG Pharmaceutical (Group) Company Limited Head Office:No.1, Yunan Street, Kaifeng, Henan Province, China Manufacturing Site: No.1, Yunan Street, Kaifeng, Henan Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is

		conducted at 30°C ±2°C / 65% ± 5% The stability study data is till 12 months.
	Ritonavir	
	Name, address of drug substance manufacturer	M/s Arene Life Sciences Private Limited Plot No. 48, 49 &50, 209, 210 & 211 Phase-II, IDA, Pashamylaram Sangareddy PIN code -502 307 Telangana, India
	Module-III Drug Substance:	The firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ±2°C / 60% ± 5% RH. The stability study data is till 24 months.
	Nirmatrelvir Film Coated Tablets	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and Comparative analysis Studies against the reference product Nirmatrelvir (Paxlovid) of Pfizer Limited have been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PAXOVIR Film Coated Tablets Blister Foil Alu Alu Bottom foil 164 mm
	Stability study data of drug product, shelf life and storage conditions	The accelerated stability study data at 40°C ±2°C / 75% ± 5% RH for 6 months and real time stability study data at 30°C ±2°C / 65% ± 5% RH for 12 months.
	Ritonavir Film Coated Tablets	
	Module-III Drug Product:	The firm has submitted data on drug products including its description, composition, pharmaceutical development, manufacture, manufacturing process, and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation

		of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and Comparative analysis Studies against the reference product Norvir of AbbVie Inc. have been submitted
	Analytical method validation/verification of product	The firm has submitted analytical method validation studies for the applied product.
	The container closure system of the drug product	PAXOVIR Film Coated Tablets Blister Foil Alu Alu Bottom foil 164 mm
	Stability study data of drug product, shelf life, and storage conditions	The firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real-time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real-time stability study data of 3 batches for 12 months.

Evaluation by PEC:

Decision of M-320: Registration Board considered and deferred for following:

i. Container closure system of the co-pack.

ii. Pharmaceutical Equivalence and Comparative Dissolution Profile with the innovator.

Firm Reply:

i. Firm has submitted comparative dissolution of Ritonavir with (Paxlovid) of Pfizer.

ii. Pack size showing 2 strips (Combipack)

Each strip contains 2 light pink colour film coated tablets of Nirmatrelvir INN 150 mg each and 1 white colour film coated tablet of Ritonavir USP 100 mg.

Decision: Approved with innovator's specifications and as per import policy. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Case No: 1 Renewal of Nitrofurantoin Tablet (038568) applied by M/s M/s Glitz Pharma, 265 Industrial Estate Kahuta Triangle Islamabad

M/s Glitz Pharma, 265 Industrial Estate Kahuta Triangle Islamabad has informed that their import consignment for 150 Kg Nitrofurantoin vide Application No. E-2421332694917 is held by Import & Export section as they are asking to provide evidence of regularization of registration of Nitrofurantoin Tablets. The Firm has requested to issue renewal of registration because they are suffering heavy demurrages at sea port. The product registration and renewal details are as under:

Reg. No.	Brand name and composition	Date of Reg.	Renewal submission details
038568	Nitrofurantoin Tablet Each tablet contains: Nitrofurantoin……...100mg (BP Specifications)	30.06.2009	Rs.10000/- dated 30.06.2014 Rs.10000/- dated 04.09.2018 (differential fee for year 2014) Rs.20000/- dated 05.11.2019 Rs.30000/- dated 01.02.2021 (differential fee for year 2019)

Submitted for consideration for regularization of registration under SRO 1005(I)/ 2017.

Decision: Registration Board regularized the renewal of Nitrofurantoin Tablet (038568) for the year 2014 and year 2019 and granted renewal w.e.f. 30.06.2021 to 29.06.2026

Case No: 2 Contract Manufacturing of Registered Products of M/s. Novartis Pharma (Pakistan) Ltd., 15-West Wharf Dockyard Road, Karachi at M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro.

M/s. Novartis Pharma (Pakistan) Ltd., 15-West Wharf Dockyard Road, Karachi has submitted request for extension in contact manufacturing of below mentioned products registered in their name manufactured at M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro. The firm has submitted following documents:

i. Fee deposit slip of 75000/- each product.
ii. Copies of DML
iii. Copies of registration letter
iv. GMP certificate of M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro.
v. Contract agreement.

The permission was valid for the period of 30months from the date of issuance of registration. The case was discussed in 317th meeting of Registration Board and deferred for following:

i. Clarification for non-compliance of timelines granted by Registration Board i.e. 30months
ii. Status of products not applied for extension in contact manufacturing in registration letter dated: 22.01.2020 and 13.02.2020

Details of the products are as under:

Sr. No.	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Validity
1.	007823	Mepresor 100mg tablets Each tablet contains: Metoprolol……100mg (Manufacturer Specification)	22.01.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
2.	006144	Mosegor sugar coated tablet Each tablet contains: Pizotifen……...0.5mg (Manufacturer Specification)	22.01.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
3.	021529	Tegral 200mg tablets Each tablet contains: Carbamazepine……200mg (Manufacturer Specification)	22.01.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
4.	041184	Trioptal 300mg tablet Each film coated tablet contains: Oxcarbazepin……300mg (Manufacturer Specification)	22.01.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027

5.	041185	Trioptal 600mg tablet Each film coated tablet contains: Oxcarbazepin……600mg (Manufacturer Specification)	22.01.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
6.	006282	Mosegor Syrup Each 5ml contains: Pizotifen…….0.25mg (Manufacturers Specification)	22.01.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
7.	021528	Caflam 50mg Tablets Each tablet contains: Diclofenac Potassium……..…50mg (Manufacturer's Specification)*	13.02.2020	75000/- dated 21.02.2022	As per decision recorded below.
8.	021525	Voltral 50 Tablets Each enteric coated tablet contains: Diclofenac sodium…..50mg (Manufacturer's Specification)*	13.02.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
9.	021524	Voltral 25 Tablets Each enteric coated tablet contains: Diclofenac sodium….25mg (Manufacturer's Specification)*	13.02.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
10.	021526	Voltral SR 100mg Tablets Each tablet contains: Diclofenac Sodium…….100mg (Manufacturer's Specification)*	13.02.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
11.	036125	Mepresor SR 200mg Tablets Each sustained release tablet contains: Metoprolol Tartrate…….200mg (Manufacturer's Specification)*	13.02.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027
12.	070803	Tegral Suspension Each 5ml contains: Carbamazepine……100mg (BP Specification)	13.02.2020	75000/- dated 21.02.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027

The firm addressed the above queries as under:

Clarification for non-compliance of timelines given by the company and approved by Registration Board i.e., 30months:

With reference to earlier approval granted, we would like to share summary of progress in compliance of said decision as follows:

- Novartis has acquired a manufacturing plant, Drug Manufacturing License 000003, the approval letter of same was issued by DRAP in October 2020 (Attached Annexure 1).
- As per commitment, we have applied products for transfer of manufacturing site, to our newly acquired site, which we shared as "Wave 1" products in our undertaking. Approval of transfer is awaited.
- Further to our commitment, we have already started validation process and stability of Wave 2 products. Application of transfer will be applied as soon as all documentation are available mandatory to secure approval.
- We acknowledge that timelines of overall project have been delayed due to challenging situations of COVID in year 2020 and 2021. We have communicated same in our first quarterly report submitted to your kind office after approval granted by Drug Registration Board, however, it will not lead to any non-compliance to prevailing contract manufacturing when approval was granted nor with new contract manufacturing policy.

Status of products not applied for extension in contact manufacturing in registration letter dated: 22.01.2020 and 13.02.2020:

With reference to above query, we would like to update authorities' status of remaining products as follows which has not been applied for contract manufacturing:

- Products applied for transfer of registration as "Wave 1", in our undertaking, i-e Lamisil 250mg Tablet, Lamisil 125mg Tablet and Annuva Dispersible Tablet doesn't require said approval.
- Attached (Annexure 2), list of products, which we have divested to local pharmaceutical company "AGP Pharma", transfer of same has been submitted and many given approvals in registration board, therefore, approval of contract manufacturing is no longer relevant for Novartis to apply.
- Other products in the list, applied for contract manufacturing as per contract manufacturing policy.

The case was placed in 320th meeting of Registration Board wherein the Board decided as under:

"Registration Board discussed that initially M/s. Novartis Pharma (Pakistan) Ltd., 15-West Wharf Dockyard Road, Karachi was given contract manufacturing approval for thirty-nine products for a period of thirty months in 2017 and 2018 under Rule of 20A of Drug (LR&A) Rules 1976. The firm was again granted an extension for a period of 30 months vide DRAP letter dated 13.02.2020 with the condition to comply the aforesaid timelines, however same was not complied by the firm as per stance narrated above. Hence the Board directed the firm to provide timelines regarding the transfer of registration of above products to their own facility".

As per above decision of the Board, the firm submitted as under:

"Novartis Pharma (Pakistan) Ltd. have submitted its case of Contract Manufacturing Extension in 2019 where registration board acceded our application and granted approval for 30 months while NVS has made following commitments

1. Novartis will setup local footprint in compliance with prevailing contract policy at that time.
2. Novartis will not request further exceptional approval and will comply with policy.

With reference to our commitments with DRAP, we would like to inform again that:

- Novartis has acquired a manufacturing plant, Drug Manufacturing License 000003, the approval letter of same was issued by DRAP in October 2020.
- As per commitment, we have applied products for transfer of manufacturing site, to our newly acquired site, depending upon production capacity, and secured approval of three products.
- Furthermore, another application of transfer is already submitted for Caflam 50mg Tablet to your office.
- We acknowledge that timelines of overall project have been delayed because of the challenging situations of COVID in year 2020 and 2021. We have communicated same in our first quarterly report submitted to your kind office after approval granted by Drug Registration Board.

Kindly refer below status summary of 39 products approved in 2020 for contract manufacturing:

- We have already received approval of 3 products i.e., Lamisil 250mg tablet, Lamisil 125mg Tablet and Annuva Dispersible Tablet which now onwards will be manufactured at Novartis plant.
- Another 2 products, Caflam 50mg is already submitted for transfer to DRAP while second Product Mepressor Tablet is on product development & stability stage at Novartis plant and will be submitted as soon as required documentation is completed.
- 17 products, which we have divested to local pharmaceutical company "AGP Pharma", transfer of same has been submitted and many given approvals in registration board, therefore, approval of contract manufacturing is no longer relevant for Novartis to apply.
- De-registration of 6 products applied, as same are divested globally.

For remaining 12 products, we request DRAP to grant us approval of contract manufacturing with GSK Jamshoro for period of 5 years, as per new contract manufacturing policy, as we would like to leverage benefit of new policy which include cost effectiveness and effective utilization of capacities".

Decision: **Registration Board considered and deliberated stance of the firm as per Rule 20-A of Drug (Licensing, Registering & Advertising) Rules, 1976 and decided as under:**

i. Granted the renewal of contract manufacturing of above products (Sr. No. 1-6 & 8-12) registered in name of M/s. Novartis Pharma (Pakistan) Ltd., 15-West Wharf Dockyard Road, Karachi from M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro with the validity period mentioned against each.

ii. **The request of M/s. Novartis Pharma (Pakistan) Ltd., 15-West Wharf Dockyard Road, Karachi for registration of Caflam 50mg Tablets (021528) at Sr. No. 7 above at their own facility shall be processed by the concerned registration section.**

Item No. III. Division of Biological Evaluation & Research

Sr. No.	Details of application	No. of Cases
A	Imported Human Biologicals from Non-Reference Countries	1
B	Local Human Biologicals	6
C	Imported Veterinary Biologicals from Reference Countries	1
D	Imported Veterinary Biologicals from Non-Reference Countries	3
E	Miscellaneous/ Deferred Cases	14
Total		25

Sr. No.	Assistant Director	Designated No.	No. of Cases
1.	Mr. Hafiz Ahsan	AD-I	6
2.	Mr. Saadat Ali Khan	AD-II	7
3.	Ms. Haleema Shareef	AD-III	8
4.	Mr. M. Kashif	AD-IV	4

Cases of AD-I (Mr. Hafiz Ahsan)

A: Imported Human Biological product from Non-reference countries:

1.	**Name, address of Applicant / Importer**	**M/s The Searle Company Limited, F-319, S.I.T.E. Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No:** 029 **Address:** Plot No. F-319 SITE, Karachi. **Validity: 08-01-2023** **Status:** License to sell drugs as a distributor.
	Name and address of marketing authorization holder (abroad)	M/s PT. Sanbe Farma (Sterile Preparation Plant), Jl. Industri Cimareme No. 8, Desa Cimareme, Kecamatan Ngamprah, Kabupaten Bandung Barat, Indonesia.
	Name, address of manufacturer(s)	M/s PT. Sanbe Farma (Sterile Preparation Plant), Jl. Industri Cimareme No. 8, Desa Cimareme, Kecamatan Ngamprah, Kabupaten Bandung Barat, Indonesia.
	Name of exporting country	Indonesia
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The Firm has submitted legalized copy of CoPP (No. RG.01.05.32.321.01.21.2365) dated 22-01-2021 issued by National Agency of Drug and Food Control, JI. Percetakan No. 23, Jakarta, Indonesia for HEPAGUSAN solution for injection. The CoPP confirms free sale status of the product in the exporting country as well as conformance of facilities and operations to GMP as recommended by WHO through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific Letter of Authorization from Coordinator of International Regulatory Affairs of PT Sanbe Farma, Indonesia. According to the letter, the firm *M/s PT Sanbe Farma* authorizes "The Searle Company Limited" as exclusive partner for the said product and officially authorized to submit application to Drug Regulatory Authority of Pakistan. The letter was issued on 16-10-2019.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 20903 (R&I); Dated 25-07-2022
	Details of fee submitted	Rs. 150,000/-; Dated 22-04-2021
	The proposed proprietary name / brand name	**Hepagusan Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Heparin Sodium……5000 IU
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Finished product specifications	BP specifications
	Proposed Pack size	Box of 10 Vials @ 5 ml /vial
	Proposed unit price	As per DPC
	Shelf Life	02 Years
	Storage Conditions	≤ 30 °C
	The status in reference regulatory authorities	Heparin Panpharma 5000 IU / ml solution for injection of M/s Panpharma, (MHRA approved).
	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Name, address of drug substance manufacturer	M/s Syntex S.A.Luis de Sarro 501 (B1838DOK) Luis Guillon, Provincia de Buenos Aires – Rep. Argentina.
	Module-III Drug Substance:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Drug Substance at Zone II conditions. The real time stability data conducted at 25°C ± 2°C/60% ± 5% RH is for 48 months. HBH1909, HBH1910, HBH1911
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of Heparin sodium injection Assay.
	Container closure system of the drug product	Type I glass vial 5ml clear, print "SANBE" Ethical red Rubber stopper Siliconized 20 mm Grey prewashed Alucap vial dia 20 mm silver embossed "SANBE".
	Stability study data of drug product	Firm has submitted stability study data of 3 batches as per Zone IV-B. The accelerated stability study data is conducted at 40°C ± 2°C/75% ±5% RH for 6 months. The real time stability study data is conducted at 30°C ± 2°C/75% ± 5% RH for 18 months. AF3404, AF3408, AF3409
	Remarks of Evaluator	
Decision: Keeping in view the availability of product in country of origin as per submitted CoPP and Heparin injection being non-rDNA pharmacopoeial product; Registration Board approved the product as per current Import Policy for finished drugs.		

B. Locally manufactured Enoxaparin Injections (Form-5)

2.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20-05-2021 valid up to 19-05-2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox 20mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……20mg
	Finished product specifications	BP Specifications
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25°C)
	International availability	Clexane 20mg/0.2ml Syringes, the product is available in PFS in the said strength & volume, (MHRA approved)
	Products already registered in Pakistan	Clexane 20mg/0.2ml and the product is available in PFS
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No. 42543 & 15484 dated 13-12-2018 & 23-08-2019 Fee Submitted: Rs.20,000/- dated 10-12-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 0.2ml PFS is available in reference country.

3.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd.,** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20-05-2021 valid up to 19-05-2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox 40mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……40mg
	Finished product specifications	BP Specifications
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25°C)
	International availability	Lovenox 40mg/0.4ml the product is available in PFS in the said strength & volume, (USFDA approved)
	Products already registered in Pakistan	Clexane 40mg/0.4ml but the product is available in PFS
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No. 42544 & 15484 dated 13-12-2018 & 23-08-2019 Fee Submitted: Rs.20,000/- dated 10-12-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 0.4ml PFS is available in reference country.
4.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20-05-2021 valid up to 19-05-2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox 60mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……60mg
	Finished product specifications	BP Specifications
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25°C)
	International availability	Lovenox 60mg/0.6ml the product is available in PFS in the said strength & volume, (USFDA approved)
	Products already registered in Pakistan	Clexane 60mg/0.6ml but the product is available in PFS
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No. 42545 & 15484 dated 13-12-2018 & 23-08-2019 Fee Submitted: Rs.20,000/- dated 10-12-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 0.6ml PFS is available in reference country.
5.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021

		GMP: Last GMP conducted on 20-05-2021 valid up to 19-05-2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox 80mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……80mg
	Finished product specifications	BP Specifications
	Pharmacological Group	Anti-thrombotic agent
	Shelf life	24 Months (Store below 25°C)
	International availability	Lovenox 80mg/0.8ml the product is available in PFS in the said strength & volume, (USFDA approved)
	Products already registered in Pakistan	Clexane 80mg/0.8ml, the product is available in PFS
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No. 42546 & 15484 dated 13-12-2018 & 23-08-2019 Fee Submitted: Rs.20,000/- dated 10-12-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 0.8ml PFS is available in reference country.
6.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20-05-2021 valid up to 19-05-2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox 100mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium..……100mg
	Finished product specifications	BP Specifications
	Pharmacological Group	Anti-thrombotic agent
	Shelf life	24 Months (Store below 25°C)
	International availability	Lovenox 100mg/ml the product is available in PFS in the said strength & volume, (USFDA approved)
	Products already registered in Pakistan	Clexane 100mg/1ml but the product is available in PFS
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No. 42547 & 15484 dated 13-12-2018 & 23-08-2019 Fee Submitted: Rs.20,000/- dated 10-12-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 1 ml PFS is available in reference country.

Data as per guidelines of 289th meeting of Registration Board;

For Bulk Concentrate Import, Local formulation Filling:

i.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Legalized Copy of GMP Certificate No.SD 20180757 dated 30-08-2018 issued by Shandong Food and Drug Administration, China. Manufacturer and its address: Dongying Tiandong Pharmaceutical Co., Ltd. No.1236, Nan-er Road, Dongying City, Shandong Province, China
ii.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished	Legalized Copy of FSC Certificate No.: 2018-001 dated 01-08-2018 issued by Shandong Food and Drug Administration of People's Republic of China.

	product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	
iii.	The firm shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the similar efficacy and safety to innovator product covering following requirements:	
	a) The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).	The firm has submitted physicochemical Characterization performed by the bulk manufacturer. The comparison has not been performed with innovator. 1.Molecular mass and molecular mass distribution. 2.HPLC-MS 3.NMR • ^{1}H NMR: • ^{13}C NMR: 4.UV: 5.Sodium content 6. Molar ratio of sulfate ions to carboxylate ions
	b) The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.	**Equivalence of heparin source material:** R: The starting material of generic Enoxaparin (manufactured by Tiandong) is porcine crude heparin, and no ruminant gene is detected as per qPCR.
	c) The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.	**Not submitted**
	d) The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	**Not submitted.**
	e) The fifth criterion for establishing sameness of enoxaparin is equivalence of in-vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.	**Not submitted.**
iv.	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	NA

v.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	48 months real time stability study data at 25°C ± 2°C, 60%RH ± 5% RH & 6 months accelerated stability study at 40°C ± 2°C, 75% RH ± 5% RH of drug substance from bulk manufacturer.
vi.	The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk as detailed in Pharmacopoeial monograph of Enoxaparin Sodium.	The firm has performed the tests on Enoxaparin sodium bulk as per pharmacopoeia.
vii.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months stability data on all the batches along with all the tests as detailed in Pharmacopoeial monograph of Enoxaparin Sodium Injection.	The firm has submitted stability study data sheets of three batches of enoxaparin sodium injection PFS for the all applied strengths as per Zone IV-A conditions.
viii.	The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used: SDS-PAGE for individual proteins GC-MS for lipid impurities Threshold ® Total DNA Assay System for DNA content.	**Not submitted**
ix.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	**Not submitted**
x.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Commitment of company letter has been submitted.
xi.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Commitment of company letter has been submitted.
xii.	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	**Not submitted**
xiii.	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	**Not submitted**

Remarks of Evaluator:

- Equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species.
- Equivalence of *in-vitro* biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time
- Equivalence of in-vivo pharmacodynamic (PD) profile in human volunteers based on measurements of in vivo anti-Xa and anti-IIa profiles.
- Performance of suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc.
- Agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.
- Relevant commitments as required by Registration Board in its 281st meeting.

Proceedings: **Registration Board was apprised that application is still deficient for submission of following points:**

i. **The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).**

ii. **The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph**

standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.

iii. **The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.**

iv. **The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.**

v. **The fifth criterion for establishing sameness of enoxaparin is equivalence of in-vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.**

Decision: Registration Board decided as follows:

i. **Submission of relevant documents as mentioned in above 5 points. Moreover, local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The techniques may be used like SDS-PAGE for individual proteins, GC-MS for lipid impurities, Threshold ® Total DNA Assay System for DNA content.**

ii. **Agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.**

iii. **Commitment that "If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect".**

iv. **Commitment that "All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to".**

Cases of AD-II (Saadat Ali Khan)

A. Imported Human Biological from Non-reference countries

7	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	M/S Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd. No 399 Libing Road China (Shanghai) and pilot free trade zone (Formulation (**dilution), filling, testing & packing**)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form 5-F Dy. No 13133 Dated 06-05-2021
	Details of fee submitted	Fee Submitted: Rs.20,000/- dated 26-03-2021.
	Brand Name + Dosage Form + Strength	**Momentum** Solution for Injection
	Composition	Each vial after reconstitution contains 50 mg of etanercept in 1 ml.
	Dosage form of applied drug	Lyophilized powder for injection
	Pharmacotherapeutic Group of (API)	Act as IMMUNO SUPPRESSANT Tumor necrosis factor receptor fusion protein
	Reference to Finished product specifications	As per innovator's specification
	Proposed Pack size Proposed unit price	1's Vial /As per DPC
	Shelf Life	24 Months
	Storage Conditions	(2^0C-8^0C)
	The status in reference regulatory authorities	"Enbrel" registered product of Immunex Corporation (Amgen) in USA approved by FDA
	For generic drugs (me-too status)	Enbrel (062228) Wyeth (Pfizer) Pakistan Momentum in 25mg (091268) Macter International ltd.
	Module-II (Quality Overall Summary	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions at -20 ℃ for 36months. The accelerated stability data is conducted at 30℃ ± 2 ℃ /60% ± 5%RH for 10 days for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	USP type-I clear glass Vials with 13mm single slit butyl grey rubber stopper & 13mm Flip off aluminum caps.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (two pilot scale & one lab scale) at long term conditions at 5±3°C for 06 months. The accelerated stability data is conducted at 25±2°C 60±5%RH for 6 months

Documents required as per 297th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)	**Documents submitted by firm**

The firms shall provide legalized GMP certificate (issued by relevant regulatory authority) of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin. Submission of valid GMP is exempted, if valid GMP status is evident from official website of regulatory authority of country of origin.	Legalized copy of GMP in case of its already registered product Momentum 25mg but it has been expired on 29-09-2021. Now the firm has submitted copy of new GMP along with verification link which was verified on 19th September, 2022. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9MTQ3MzkmaXRlbUlkPTJjOWJhMzg0NzU5Yzk1NzcwMTc1OWNjMjcxNmMwMjMw
The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority (or its website) as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk.	Legalized CoPP of 25mg was already submitted by the firm in case of its already registered product Momentum 25mg but the CoPP expired on December, 2018. Now the firm has submitted copy of new CoPP which can be verified online on the official website of NMPA china by the given link was verified on 19th September, 2022. https://www.nmpa.gov.cn/datasearch/en/search-info-en.html?nmpa=aWQ9Nzk0MiZpdGVtSWQ9MmM5YmEzODE3OWQwOGY0ZjAxNzlkMGYyZmRhMjAwMzU=
The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the biosimilarity. However, it will not be required if the finished drug product was approved before implementation of biosimilarity in the said country and finished drug product is still freely available and the firm shall provide the safety, efficacy data of finished drug product as per applicable regulatory requirements at that time.	Provided & Evaluated below
The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	The firm has submitted that lot release is not required in country of orgin (BulK provided country).
The firm shall provide the 6 months accelerated and real time stability studies for drug substance & drug product manufactured locally.	Provided
The local manufacturer shall manufacture three trial batches (quantity sufficient to meet the complete testing up to the assigned shelf life both for real time and accelerated stability studies) of the finished biological product to finalize the formulation and then perform tests as per following order: i. Latest Pharmacopoeia ii. Innovator Product iii. Reference Biotherapeutic Product iv. In case aforementioned tests are not available then tests as adopted by drug substance manufacturer shall be followed.	Provided results for the following tests with comparative with Enbrel (Wyeth Pakistan Ltd.) : • Identification and purity by SDS-PAGE, • Purity by Gel Filtration Chromatography • Potency (Protein Concentration) by bicinchoninic acid assay (BCA) Method. • Biological Activity by Cytotoxicity Inhibition assay. • Endotoxin Test by Gel Clot Method • Sterility Test by Membrane Filtration Technique The following tests are also performed: Physical appearance (before & after re-constitution), Reconstitution Time, Particulate Matter (After Reconstitution) Moisture Content (by Karl Fischer), PH, Protein content by BCA Method, Specific Bioactivity, lmmuno identification Western Blotting, Molecular weight identification by SOS-PAGE (Reducing, silver Staining), Purity by SOS- PAGE (Reducing, Silver Staining), Purity by Gel Filtration-HP LC, Bacteria Endotoxin, sterility test.

The manufacturer shall perform all tests locally as mentioned on Certificate of analysis of finished product of drug substance supplier in case of non-pharmacopoeial product.	Submitted as mentioned above
The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form in any country of the world (if available).	Provided
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	The firm has submitted copy of supply agreement wherein it has been mentioned that any changes in the process shall be communicated to DRAP. However, the name of bulk manufacturer mentioned is "**Shanghai CP** Guojian Pharmaceutical co. ltd. 399 Libing Road, **Zhangjiang Hi-tech Park**, Shanghai P.R. China" while in provided GMP/FSC the name & address of Bulk manufacturer is "**Sunshine** Guojian Pharmaceutical (Shanghai) co. ltd. 399 Libing Road, China (Shanghai) **Pilot Free Trade Zone**, China" **The firm has submitted clarification letter from its manufacturer where it has been mentioned that manufacturer name has been changed & nomenclature of the adrres has been also changed while the site remain the same.**
Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	The firm has provided SOP for Pharmacovigilance Surveillance. The firm has also provided Commitment on on stamp paper mentioning the said statement.
The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Commitment provided on stamp paper by the applicant.
If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Commitment provided on stamp paper by the applicant.
All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Commitment provided on stamp paper by the applicant.
For the already registered drugs for local manufacturing, the current guidelines shall apply at the time of renewal of product.	

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.	
WHO Bio-similarity guidelines	**Data submitted by the firm**

Quality Comparison Physicochemical characterization	**Physicochemical Characterization** **<u>Structure Characterization</u>** i) Primary Structure ii) Relative Molecular Weight by Electrophoresis iii) Molecular Weight by SEC-DLS iv) Peptide Mapping BY HPLC v) Peptide Mass Mapping vi) N-terminal Amino Acid Sequence vii) C-terminal Amino Acid Sequence by LC-MS/MS **Secondary Structure** by Far UV CD Spectrum by Near UV CD Spectrum) **Posttranslational Modification** i) N-glycan Analysis ii) Content of Sialic Acid
Biological Activity & Immunochemical properties	Biological activity in vitro for Yisaipu and Enbrel is tested by TNFα neutralization killing test based on L929 cell with the active reference produced. **Receptor Binding Activity** ELISA Test **Affinity Analysis:** Binding of rhTNFR Affinity with antigen TNF- α **Affinity with Fc segment key receptor** Affinity with FcRn receptor Affinity with FcγRIa receptor Affinity with FcγRIIa receptor Affinity with FcγRIIb receptor Affinity with FcγRIIIa receptor Binding activity with complement C1q **Antibody-dependent cell-mediated cytotoxicity (ADCC)** **Complement dependent cytotoxicity (CDC)** **C-terminal lysine charge variants analysis**
Impurities	**Purity** i) SEC-HPLC Purity ii) HIC-HPLC Purity iii) SDS-PAGE Purity iv) Electric Charge Analysis
Stability Studies	Stability studies are provided.
Non-clinical Studies i. In-vitro Studies ii. In-vivo Studies	**Pharmacology** <u>In-vitro Studies</u>: Comparative Primary Pharmacodynamics i. Murine L929 cells ii. Biacore T100 **Secondary Pharmacodynamics** (**In-vivo Studies.)** -Collagen-induced arthritis (CIA)model in mice -Adjuvant-induced arthritis (AA)model in rats -Dalactos amine-induced neutralizing model in mice **Safety Pharmacology** **Pharmacokinetics** Toxicology studies **i) Single Dose Toxicity (Kunming mice)** **ii) Repeated Dose Toxicity (rhesus model)** **iii) Local Tolerance**
Clinical Studies	**Phase I Clinical Study** Compare the pharmacokinetic properties and tolerability of two formulations of Etanercept in Mexican healthy volunteers to establish biocomparability and non-biocomparability between both. **Phase II Clinical Study** i. Observe the safety and efficacy of rhTNFR: Fc (INN: ETANERCEPT) after administration in the patients with moderate or severe active rheumatoid arthritis (RA).' ii. Randomized double blind, placebo parallel control multi-center clinical trial for the efficacy and safety of treating ankylosing spondylitis with Yisaipu **Phase III Clinical Study** An open label, prospective, non-comparative, multicentre study to assess the safety and efficacy of Etanercept for injection 25mg in patients with moderate to severe active rheumatoid arthritis.

	Phase IV Clinical Study A multi-center and open study to evaluate the safety and efficacy of the recombinant human tumor necrosis factor receptor II antibody fusion protein for injection in the treatment of active rheumatoid arthritis (RA).
Remarks	Phase I is submitted comparative while phase-III clinical study is non-comparartive. However, its already registered strength of the same product i.e. Momentum 25mg was approved & registered on the basis of the same data. And M/s Getz Pharma also imported the same molecule from the same manufacturer which was also approved & registered on the basis of the same clinical trial data.
Decision: Keeping in view the data submitted by the firm in light of guidelines of 297th meeting Registration Board approved the product.	

C. Imported Veterinary Biologicals from Reference Countries:

8	**Name of Importer &** Address	**M/s Hipra Pakistan (Private) Limited,** 3rd floor, plot no 8, block CCA, Phase 6-C, DHA, Lahore **Go down** 2nd Warehouse on Left side, Street no 5, Gajjumata Nadir Chowk, Hazara Chowk, Industrial Area Ferozpur Road, Distt Lahore
	DSL Details	License to sell drug as distributor No. 0011000 0004579 valid till 19-Feb-2022
	Name of Manufacturer & Address	Laboratorios HIPRA, S.A, Avda. La Selva, 13517170 Amer (Girona) Spain
	Brand Name/Dosage Form	**Evant 10,000 dose** Suspension and Solvent for oral spray
	Composition	Each dose of vaccine contains: Eimeria acervulina, strain 003……332-450 Eimeria maxima, strain 013…….196-265 Eimeria mitis, strain 006…….293-397 Eimeria praecox, strain 007…….293-397 Eimeria tenella, strain 004……..276-374 **Composition of Solvent (Hipramune T):** Montanide IMS (**Adjuvant)** Blue coloring Agent Red coloring Agent Vanillin
	Finished Product Specifications	European Pharmacopeia
	Pharmacological Group	Live attenuated vaccine, avian coccidiosis
	Shelf Life & Storage	10 months at 2-8ºC
	Products already Registered in Pakistan	The product already registered in 1000 & 5000 doses
	Type of Form, Dy. No & Date of Application Fee Submitted	Form – 5A Dy. No 20523 Dated 28-07-2021 Fee Submitted: Rs. 150,000 /- dated 09-07-2021
	Demanded Price&Pack Size	Decontrolled 10,000 dose Vial
	General Documentation	Legalized Certificate of Pharmaceutical Product (CoPP) No 05/20/150457 dated 19-10-2020 issued by EMA.
	Decision	**Keeping in view legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**

D. Imported Veterinary Biologicals from Non-Reference Countries:

9	**Name of Importer**	**ICI Pakistan Limited** **ICI House, 5 West Wharf Karachi-Pakistan**
	DSL details	License to sell drug as distributor No.020 valid till10-03-2023

	Name of Manufacturer	M.s.Choong Ang Vaccine Laboratories Co., Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon, 34055, Korea
	Brand Name + Dosage Form + Strength	PoulShot® LaSota
	Composition	Each dose contains: Newcastle disease virus (NDV, LaSota strain) ..... $\geq 10^{6.0}EID_{50}$
	Finished product specifications	Ph. Eur. Specifications
	Pharmacological Group	Live Veterinary Vaccine
	Shelf life	24 Months (Store at 2°C -8°C)
	Products already registered in Pakistan	Medivac ND Lasota 2000 (Imported by Hilton)
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy No. 8381 Dated: 15.03.2021, Dy No. 26224 dated 16-09-2022 Fee Submitted: Rs. 100000/- dated 24.02.2021
	Demanded Price / Pack size	2000 Doses Vials
	General Documentation	• Legalized FSC having Certificate No. M2100613 issued by Animal & Plant Quarantine Agency of the Ministry for Agriculture Food & Rural Affairs of Korea dated 02.02.2021. • Legalized GMP Certificate issued by Animal & Plant Quarantine Agency of Korea dated 02.02.2021.
	Decision:	**Keeping in view legalized GMP and Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**

10.	**Name of Importer**	**ICI Pakistan Limited8** **ICI House, 5 West Wharf Karachi-Pakistan**
	DSL details	License to sell drug as distributor No.020 valid till10-03-
	Name of Manufacturer	M/s. Choong Ang Vaccine Laboratories Co., Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon, 34055, Korea
	Brand Name + Dosage Form + Strength	**PoulShot® LaSota+IB**
	Composition	Newcastle disease virus (NDV, LaSota strain) ..... $\geq 10^{6.0}EID_{50}$ Infectious bronchitis virus (IBV, H120 strain) ..... $\geq 10^{2.5}EID_{50}$
	Finished product specifications	Ph. Eur. Specifications
	Pharmacological Group	Live Veterinary Vaccine
	Shelf life	18 Months (Store at 2°C -8°C)
	Products already registered in Pakistan	Medivac ND+IB 2000ds (Imported by Hilton)
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy. No. 8379 Dated: 15.03.2021, Dy No. 26224 dated 16-09-2022 Fee Submitted: Rs. 100000/- dated 24.02.2021
	Demanded Price / Pack size	2000 Doses Vial
	General Documentation	• Legalized FSC having Certificate No. M2005142 issued by Animal & Plant Quarantine Agency of the Ministry for Agriculture Food & Rural Affairs of Korea dated 22.04.2020. • Legalized GMP Certificate issued by Animal & Plant Quarantine Agency of Korea dated 22.04.2020.
	Decision:	**Keeping in view legalized GMP and Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**

B: Miscellaneous/ Deferred Cases

Case No. Imported Human Biological applied by M/s Lab Diagnostic Systems (SMC) Pvt. Ltd, Rawalpindi deferred in 320th meeting of Registration Board.

11	**Name, address of Applicant / Importer**	**Lab Diagnostic Systems (SMC) Pvt. Ltd.** **plot 36-A, PSIC SIE, Taxila Rawalpindi**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D **Address:** 36-A,PSIC,SIE,Taxila Rawalpindi

		Validity: 04/08/2024
	Name and address of marketing authorization holder (abroad)	NANJING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO., LTD located at No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China 210061 Telephone Number: +86-25-86990701 Fax Number: +86-25-86990701 D-U-N-S Number: 421297554 FEI Number: 3010625707 Last FDA Inspection Date: March 26 to April 3, 2018
	Name, address of manufacturer(s)	NANJING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO., LTD located at No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China 210061
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted copy of CoPP issued by USFDA and copy of COPP from China. The COPP specifies that the product is licensed for sale in country of origin and US. The COPP also specifies the GMP status of manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted Pakistan notarized copy of distribution certificate from **M/s** Nanjing King-Friend Biochemical Pharmaceutical co., ltd According to the letter, the firm **M/s** Nanjing King-Friend Biochemical Pharmaceutical Co., LTD**.** authorizes "M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. for the purpose of registration, distribution and marketing of the product. The letter was issued on 15/08/2022 valid up to 14/08/2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form -5F Dy. No.23288 dated: 17/08/2022, Dy. No.23946 dated: 24/08/2022, **Dy. No.26124 dated: 15/09/2022, Dy. No.26125 dated: 15/09/2022**
	Details of fee submitted	Rs: 1,50,000 dated: 17/08/2022
	The proposed proprietary name / brand name	**Hepalid** 5000IU/5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Heparin sodium: 5000 USP units
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anticoagulants
	Reference to Finished product specifications	USP
	Proposed Pack size	2's
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at 20°C -- 25°C, excursions permitted between 15°C -- 30°C
	The status in reference regulatory authorities	Heparin Sodium Injection, USP FDA Approved
	For generic drugs (me-too status)	REGISTRATION NO: 066083 Brand Name: HEPARIN RAGALAB 5000 I.U. 5ML VIAL Importer Name: Kurative Pharma International
	Module-II (Quality Overall Summary	**QOS is not as per WHO**. Firm has summarized only information related to general properties, name of manufacturers for drug substance part. Composition of Drug product, description of manufacturing process and controls, specifications analytical procedures and justification of specification, reference standard, container closure system of drug product.

	Name, address of drug substance manufacturer	Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd.MA010-1, Nanjing High & Ne Technology Development Zone, Nanjing, China, 210061 Tel: 86-25-86992106 Fax: 86-25-86990701
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions. The real time stability data is conducted at 5 ℃ ±3 ℃ RH 60%±10% for 12 months of 03 batches and 25 ± 2 ℃ /60% ± 5%RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	A proposed container closure system including Glass meeting the requirements of "Type I glass" as defined in the USP <660> was deemed to be adequate for the product. USP Type I Borosilicate glass container. **In packaging configuration & sizes only following packing are mentioned; 1000 IU/ ml (2ml vial), 10,000/ 10ml (10ml vial),** **30,0000 IU/ 30ml (30ml), 5000 IU/ ml (2ml vial), 50,000 IU/ 10ml,** **10,000 IU/ 1ml, 40,000 IU/ 4ml (5ml vial)**
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time conditions. The real time stability data is conducted at 30± 2C & 60 ±5% RH for 6 months. A statement for availability of 24 months data is provided. The accelerated stability data provided is of 03 batches and is conducted at 40± 2C & 75 ±5% RH for 06 months.
	Module-IV Non-Clinical	N/A
	Module-V Clinical	N/A
	Remarks of Evaluator	i. For point No. 3.2.S.2.2, 3.2.S.2.3, 3.2.S.2.4, 3.2.S.2.5 & 3.2.S.2.6 of CTD, the firm referred to DMF but DMF has not been provided. ii. The product is from China but the firm has submitted copy of CoPP from USFDA. And regarding China CoPP it has been mentioned that product is under registration in China. And the firm has also submitted statement from their manufacturer that legalized CoPP will be submitted by end of October, 2022. iii. In the copy of USFDA-CoPP , **the importing country Israel has been mentioned.** iv. The firm has submitted copy of CoPP issued by USFDA which can be verified by the QR code mentioned on the CoPP. However, CoPP only mentioned "***Active Ingredient (s) and amount (s) per unit dose: heparin sodium usp 5000 Units***" total number of ml (volume) is not mentioned. The same was searched on USFDA official website wherein under the **Abbreviated New Drug Application (ANDA)**: 211007 (mentioned on the submitted CoPP), three products are mentioned HEPARIN SODIUM (1,000 UNITS/ML) HEPARIN SODIUM (5,000 UNITS/ML) HEPARIN SODIUM (10,000 UNITS/ML) But total number of ml (volume) was not mentioned there as well, and no other information is available on USFDA website. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211007 v. The firm has mentioned (demanded) 5000Units/5ml vial packing in their CTD dossier i.e. covering letter, labeling information, fee receipt, QOS, point no. 1.5.2 of Module-I in all these document the firm has demanded 5000 Units/5ml but in distribution agreement, the firm has been authorized for 5000Units/mL (5ml vial).

		vi. In CTD dossiers under the packaging & container closure system neither 5000units/5ml vial nor 25000units/5mL vial is mentioned. (Already described in container closure system) vii. The firm has submitted stability study data (real time stability data) for 5000units/ml (5ml vial) is conducted at 30± 2C & 60 ±5% RH for 6 months. A statement from their manufacturer that they will submit complete stability study data once completed.

The case was deferred in 320th meeting of RB for following:

- **i.** Data related to Section 3.2.S.2.2, 3.2.S.2.3, 3.2.S.2.4, 3.2.S.2.5 & 3.2.S.2.6 of CTD.
- **ii.** Valid legalized CoPP issued by USFDA indicating demanded strength & pack size.
- **iii.** Clarification regarding difference in strength in dossier and distribution agreement.
- **iv.** Real time stability study data up to the demanded shelf life.

Reply submitted by the firm:

- Now the firm has submitted data related to S part against the mentioned sections.
- **Regarding the valid legalized CoPP issued by USFDA, the firm has submitted that it will be available by the end of October, 2022.**
- While the registration status of the product in country of orgin i.e. China, the firm has submitted that said product is only registered in USFDA, not yet registered in China.
- Regarding the difference in strength in dossier & distributor agreement, the firm has submitted the dossier documents provided for Heparin sodium dossier is uniform/same for all the strengths specially for Heparin Sodium 5000IU/ml- 5mL vial. And the applied strength of the product is Hepalid 5000IU/ml-5mL Injection (25000IU/5mL vial)
- **Regarding real time stability study data, the firm has submitted the study is ongoing & they will provide 24 months' stability data of intermediate condition of 3 commercial batches with passage of time.**

Decision: Keeping in view the approval of USFDA (Reference Regulatory Authority), Registration Board approved the product subject to compliance of current Import Policy for finished drugs & submission of valid legalized CoPP issued by USFDA.

The firm shall submit the real time stability data before issuance of Registration letter & shelf life will be granted as per the submitted real time stability study data. The Chairman Registration Board is authorized for issuance of letter after submission of said document & data.

12	**Name, address of Applicant / Importer**	**Lab Diagnostic Systems (SMC) Pvt. Ltd. plot 36-A, PSIC SIE, Taxila Rawalpindi**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi Validity: 04/08/2024
	Name and address of marketing authorization holder (abroad)	Nanjing King-Friend Biochemical Pharmaceutical Co., ltd., located at No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China 210061
	Name, address of manufacturer(s)	NANJING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO., LTD located at No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China 210061
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted copy of CoPP issued by USFDA (certificate no. 6HJ2-64TA issued June 04, 2021). The COPP specifies that the product is licensed for sale in country of origin and US. The COPP also specifies the GMP status of manufacturer.(Risk based Inspection)
	Details of letter of authorization / sole agency agreement	Firm has submitted Pakistan notarized copy of distribution certificate from **M/s** Nanjing King-Friend Biochemical Pharmaceutical co., ltd According to the letter, the firm **M/s** Nanjing King-Friend Biochemical Pharmaceutical Co., LTD**.** authorizes "M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. for the purpose of registration, distribution and marketing of the product. The letter was issued on 15/08/2022 valid up to 14/08/2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form -5F Dy. No.1150 dated: 18/08/2022, Dy. No.23945 dated: 24/08/2022
	Details of fee submitted	Rs: 1,50,000 Dated: 17/08/2022
	The proposed proprietary name / brand name	**VINOX 40mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.4ml syringe contains: 40mg enoxaparin sodium injection
	Dosage form of applied drug	IV/SC Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant (Low molecular weight heparins.)
	Reference to Finished product specifications	USP
	Proposed Pack size	2's
	Proposed unit price	As per SRO
	Shelf Life	36 months
	Storage Conditions	Store at Below 30°C
	The status in reference regulatory authorities	Lovenox (enoxaparin sodium injection) for subcutaneous and intravenous USFDA approved
	For generic drugs (me-too status)	Clexane 40mg
	Module-II (Quality Overall Summary	**QOS is not as per WHO**. Firm has summarized only information related to general properties, name of manufacturers & & justification of specification for drug substance part. Composition of Drug product, description of manufacturing process and controls, specifications analytical procedures and justification of specification, reference standard, container closure system of drug product.
	Name, address of drug substance manufacturer	Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd.MA010-1, Nanjing High & Ne Technology Development Zone, Nanjing, China, 210061
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions. The real time stability data is conducted at 25 ± 2°C 60 ± 5% R for 36 months of 03 batches and 40±2 °C 75 ± 5% RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	A proposed container closure system including one mL syringe-BD Hypak SCF (sterile clean and ready-to-fill) including barrel one mL USP type I class , needle stainless steel 304, rigid needle shield rubber, rubber stopper, plunger rod, and safety device.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time conditions. The real time stability data is conducted at 30± 2C & 60 ±5% RH for 36 months (by applying bracketing principle on

		30mg/0.3ml and 100mg/1ml strengths). The accelerated stability data provided is of 03 batches and is conducted at 40± 2C & 75 ±5% RH for 06 months.
	Module-IV Non-Clinical	N/A
	Module-V Clinical	N/A
13	**Name, address of Applicant / Importer**	**Lab Diagnostic Systems (SMC) Pvt. Ltd.** **plot 36-A, PSIC SIE, Taxila Rawalpindi**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi Validity: 04/08/2024
	Name and address of marketing authorization holder (abroad)	Nanjing King-Friend Biochemical Pharmaceutical Co., ltd., located at No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China 210061
	Name, address of manufacturer(s)	NANJING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO., LTD located at No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China 210061
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted copy of CoPP issued by USFDA (certificate no. CE9E-AHA6 issued June 07, 2021). The COPP specifies that the product is licensed for sale in country of origin and US. The COPP also specifies the GMP status of manufacturer.(Risk based Inspection)
	Details of letter of authorization / sole agency agreement	Firm has submitted Pakistan notarized copy of distribution certificate from **M/s** Nanjing King-Friend Biochemical Pharmaceutical co., ltd According to the letter, the firm **M/s** Nanjing King-Friend Biochemical Pharmaceutical Co., LTD**.** authorizes "M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. for the purpose of registration, distribution and marketing of the product. The letter was issued on 15/08/2022 valid up to 14/08/2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form -5F Dy. No.1149 dated: 18/08/2022, Dy. No.23945 dated: 24/08/2022
	Details of fee submitted	Rs: 1,50,000 Dated: 17/08/2022
	The proposed proprietary name / brand name	**VINOX 60mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.6ml syringe contains: 60mg enoxaparin sodium injection
	Dosage form of applied drug	IV/SC Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant (Low molecular weight heparins.)
	Reference to Finished product specifications	USP
	Proposed Pack size	2's
	Proposed unit price	As per SRO
	Shelf Life	36 months
	Storage Conditions	Store Below 30°C
	The status in reference regulatory authorities	Lovenox (enoxaparin sodium injection) for subcutaneous and intravenous USFDA approved
	For generic drugs (me-too status)	Clexane 40mg

	Module-II (Quality Overall Summary	**QOS is not as per WHO**. Firm has summarized only information related to general properties, name of manufacturers & & justification of specification for drug substance part. Composition of Drug product, description of manufacturing process and controls, specifications analytical procedures and justification of specification, reference standard, container closure system of drug product.
	Name, address of drug substance manufacturer	Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd.MA010-1, Nanjing High & Ne Technology Development Zone, Nanjing, China, 210061 Tel: 86-25-86992106 Fax: 86-25-86990701
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions. The real time stability data is conducted at 25 ± 2°C 60 ± 5% R for 36 months of 03 batches and 40±2 °C 75 ± 5% RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	A proposed container closure system including one mL syringe-BD Hypak SCF (sterile clean and ready-to-fill) including barrel one mL USP type I class , needle stainless steel 304, rigid needle shield rubber, rubber stopper, plunger rod, and safety device.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time conditions. The real time stability data is conducted at 30± 2C & 60 ±5% RH for 36 months (by applying bracketing principle on 30mg/0.3ml and 100mg/1ml strengths). The accelerated stability data provided is of 03 batches and is conducted at 40± 2C & 75 ±5% RH for 06 months.
	Module-IV Non-Clinical	N/A
	Module-V Clinical	N/A
	Remarks of Evaluator	
14	**Name, address of Applicant / Importer**	**Lab Diagnostic Systems (SMC) Pvt. Ltd. plot 36-A, PSIC SIE, Taxila Rawalpindi**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi Validity: 04/08/2024
	Name and address of marketing authorization holder (abroad)	Nanjing King-Friend Biochemical Pharmaceutical Co., ltd., located at No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China 210061
	Name, address of manufacturer(s)	NANJING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO., LTD located at No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China 210061
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted copy of CoPP issued by USFDA (certificate no. PYCS-KTDV issued June 07, 2021). The COPP specifies that the product is licensed for sale in country of origin and US. The COPP also specifies the GMP status of manufacturer.(Risk based Inspection)
	Details of letter of authorization / sole agency agreement	Firm has submitted Pakistan notarized copy of distribution certificate from **M/s** Nanjing King-Friend Biochemical Pharmaceutical co., ltd According to the letter, the firm **M/s** Nanjing King-Friend Biochemical Pharmaceutical Co., LTD**.** authorizes "M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. for the purpose of registration, distribution and marketing of the product. The letter was issued on 15/08/2022 valid up to 14/08/2023

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form -5F Dy. No.1152 dated: 18/08/2022, Dy. No.23945 dated: 24/08/2022
	Details of fee submitted	Rs: 1,50,000 Dated: 17/08/2022
	The proposed proprietary name / brand name	VINOX 80mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.8ml syringe contains: 80mg enoxaparin sodium injection
	Dosage form of applied drug	IV/SC Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant (Low molecular weight heparins.)
	Reference to Finished product specifications	USP
	Proposed Pack size	2's
	Proposed unit price	As per SRO
	Shelf Life	36 months
	Storage Conditions	Store Below 30°C
	The status in reference regulatory authorities	Lovenox (enoxaparin sodium injection) for subcutaneous and intravenous USFDA approved
	For generic drugs (me-too status)	Clexane 40mg
	Module-II (Quality Overall Summary	**QOS is not as per WHO**. Firm has summarized only information related to general properties, name of manufacturers & & justification of specification for drug substance part. Composition of Drug product, description of manufacturing process and controls, specifications analytical procedures and justification of specification, reference standard, container closure system of drug product.
	Name, address of drug substance manufacturer	Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd.MA010-1, Nanjing High & Ne Technology Development Zone, Nanjing, China, 210061
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions. The real time stability data is conducted at 25 ± 2°C 60 ± 5% R for 36 months of 03 batches and 40±2 °C 75 ± 5% RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	A proposed container closure system including one mL syringe-BD Hypak SCF (sterile clean and ready-to-fill) including barrel one mL USP type I class , needle stainless steel 304, rigid needle shield rubber, rubber stopper, plunger rod, and safety device.

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time conditions. The real time stability data is conducted at 30± 2C & 60 ±5% RH for 36 months (by applying bracketing principle on 30mg/0.3ml and 100mg/1ml strengths). The accelerated stability data provided is of 03 batches and is conducted at 40± 2C & 75 ±5% RH for 06 months.
	Module-IV Non-Clinical	N/A
	Module-V Clinical	N/A
	Remarks of Evaluator	i. The product is from China but the firm has submitted copy of CoPP from USFDA. And regarding China CoPP it has been mentioned that product is under registration in China. And the firm has also submitted statement from their manufacturer that legalized CoPP will be submitted by end of October, 2022. ii. In the copy of USFDA-CoPP , **the importing country Israel has been mentioned.** iii. The firm has submitted copy of CoPP issued by USFDA which can be verified by the QR code mentioned on the CoPP. However, the same was searched on USFDA official website wherein the products are available. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211007 iv. Data as per guideline approved in 289th meeting of Registration Board as regulatory requirements for registration of Enoxaparin Injections, not submitted.

Decision:

Registration Board deferred the case for submission of following by the firm:

i. Valid legalized CoPP issued by USFDA.

ii. Data of Enoxaparin Sodium equivalence in light of guidelines of 289th meeting of Registration Board.

Reply submitted by the firm:

- Regarding the valid legalized CoPP issued by USFDA, the firm has submitted that it will be available by the end of October, 2022.
- While the registration status of the product in country of orgin i.e. China, the firm has submitted that said product is only registered in USFDA as well as registered in China. Copy of Chinese CoPP is also submitted.
- Regarding data of Enoxaparin Sodium equivalence in light of guidelines of 289th meeting of Registration Board, the firm has submitted the following data.

The firm has submitted the following data as per requirements of 289th meeting of Registration Board:

Required Documents	**Documents Provided by the Firm**
Equivalence of physicochemical properties, such as:	
a. Molecular weight distribution using size exclusion chromatography	i. Molecular mass distribution and proportion ii. %1, 6-anhydro derivatives iii. Ratio of sulfate ions to carboxylate ions iv. UV Absorption and specific absorbance at 231 nm
b. Chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).	i. Chain mapping by Gel Filtration Chromatography (GFC) ii. Chain mapping by strong anion exchange HPLC (SAX-HPLC) iii. Proton nuclear magnetic resonance (1H-NMR) iv. Heteronuclear single quantum coherence (HSQC) v. Intact chain mapping by LCMS
Equivalence of heparin source material (i.e. heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (i.e. cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.	• Fresh pig's small intestine is collected and squeezed to get porcine intestinal mucosa. Porcine intestinal mucosa is then digested and heparin is adsorbed on an ion exchange resin (Intermediate A). • After the washing and elution of the resin, further steps of precipitation and drying lead to crude heparin (Intermediate B). • Crude heparin (Intermediate B) is dissolved in water, submitted to enzymolysis and then purified on resins. Heparin sodium (Intermediate C) is obtained after several steps including oxidation, ultra-filtration, fractionation and a final precipitation in ethanol.

	• Enoxaparin sodium is manufactured in three stages, starting from the heparin sodium which undergoes a step of salification to get the quaternary ammonium salt of heparin (Intermediate I). The salification step is followed by an esterification step to form the ester salt of heparin (Intermediate II). Enoxaparin sodium is finally isolated after depolymerization and purification steps.
Equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by following: a. Capillary Electrophoresis (CE) b. Reverse phase high-performance liquid chromatography (RP-HPLC) c. Strong anion exchange HPLC (SAX-HPLC) d. Mass spectroscopy e. Nuclear magnetic resonance (NMR) spectroscopy. f. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.	i. Disaccharide building block by strong anion exchange HPLC (SAX-HPLC) ii. Fragment mapping (Heparinase I/II/III) by strong anion exchange HPLC (SAX-HPLC) iii. Fragment mapping (heparinase I/II/III) by liquid chromatography – mass spectrometry (LC-MS) iv. Dp6 mapping (heparinase I/II/III) by liquid chromatography – mass spectrometry (LC-MS) v. Nitrous acid (HONO) depolymerisation disaccharide mapping by liquid chromatography – mass spectrometry (LC-MS) vi. Tetrasaccharides (dp4) analysis by strong anion exchange HPLC (SAX-HPLC) vii. Tetrasaccharides (dp4) sequences by reversed-phase ion-pair liquid chromatography- electrospray ionization - mass spectrometry (RPIP-ESI-MS and RPIP-ESI-MS/MS) viii. Oligosaccharide mapping by liquid chromatography – mass spectrometry (LC-MS) (dp6/8/10)
Equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	i. Anti-factor Xa & Anti-factor IIa activity by using Biophen Heparin Anti-Xa (2 Stages) and Biophen Heparin Anti-IIa (2 Stages) commercial kits. ii. The anticoagulant activity of the biosimilar enoxaparin drug product is analysed and compared with Lovenox®/Clexane® based on aPTT (Activated Partial Thromboplastin Time) and Heptest prolongation time
Equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.	A monocentric, randomized, open-label, single-dose, two-period, crossover study to assess the pharmacokinetic and pharmacodynamic equivalence of Reference Product Lovenox® 10000 IU/1 mL solution for injection in prefilled syringe and test formulation of Enoxaparin Ledraxen 10.000 IE (100 mg)/1 ml Injektionslösung in einer Fertigspritze following subcutaneous administration in healthy subjects in fasting conditions
Remarks of Evaluator:	
Decision: Keeping in view the approval of USFDA (Reference Regulatory Authority), Registration Board approved the product subject to compliance of current Import Policy for finished drugs & submission of valid legalized CoPP issued by USFDA. The Chairman Registration Board is authorized for issuance of letter after submission of said document.	

Cases of AD-III (Haleema Shareef)

B; Imported Veterinary Biologicals from Non-Reference Countries:

15	**Name and address of Importer**	**M/s. Brand Station, 89 A2, Wapda Town Extension, Lahore, Pakistan**
	Detail of DSL	Address: M/s. Brand Station 69 Wocland villas Lahore, near raiwind road, Lahore. Valid till: 10-08-2027
	Name and address of Manufacturer	**Manufacturer:** M/s. Yebio Bioengineering Co., Ltd Adress: No.260 Heyuan Road Hongdao, Qingdao, China
	Name of exporting country	China

	Brand Name +Dosage Form + Strength	Yevac ND vaccine 500ml
	Diary No. Date of R& I & fee	Dy. No. R&I Dated 24-01-2022 Rs. 150,000/- (Slip No. 5830267467)
	Composition	Each dose (0.5ml) contains: Newcastle Disease Virus Strain Lasota $\geq 10^{8.1}$ EID_{50} before inactivation.
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	24months----(2-8°C)
	Document Details	Firm has submitted following: Original legalized FSC Original legalized GMP Original legalized sale agency agreement: it is expired now
	Pack size & Price	500ml: Decontrolled
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Reg. No. 89766 Al-Asar Enterprises, Multan MYVAC K811 (Inactivated Newcastle disease vaccine B1 Type LaSota) Each dose contains: Inactivated New castle disease virus LaSota strain $\geq 10^{8.5} EID_{50}$
	Remarks of Evaluator	1. Firm has submitted application for change in address and fee on 19.09.2022. **2. Sale agency agreement was valid at the time of submission and get expired now.** 3. In Labelling and Prescribing Information New Castle disease virus Lasota strain (CVCC AV 1615) is written. What does this number (CVCC AV 1615) indicate, is it a name of strain or otherwise? **Firm has submitted that labeling of Yevac ND vaccine contain the word CVCC AV1611 which is Newcastle disease virus Beijing strain.*
	Decision: Keeping in view legalized GMP and Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs & submission of valid Sole agency agreement/authorization letter.	

B: Miscellaneous/ Deferred Cases

Case No. 16 Imported Veterinary Biological applied by M/s Vet Line International, Lahore deferred in 316th meeting of Registration Board.

Name and address of Importer	**M/s Vet Line International,** 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore.
Detail of DSL	**M/s Vet Line International,** Address: Basement & Ground, Floor 939-A, Block J, Phase 1, LDA Avenue-1, District Lahore Valid till: 09-Feb-2023
Name and address of Manufacturer	**Manufacturer of Drug:** Nanjing Bio-Pharmaceutical Factory of QYH BIOTECH Co., LTD No. 33 Xiaohang Road, Yuhuatai District, Nanjing City, Jiangsu Province, P.R China
Name of exporting country	China
Brand Name +Dosage Form + Strength	**Newcastle disease virus vaccine (Inactivated)**
Diary No. Date of R& I & fee	Dy. No. 8032 R&I Dated 11-03-2021 Rs. 100,000/- Dated 11-03-2021

Composition	(Inactivated vaccine) Each 0.1ml contains: Newcastle disease virus A-VII Strain $\geq 10^8$ EID_{50} before inactivation.
Pharmacological Group	Biologicals
Type of Form	Form-5A
Finished Product Specification	Manufacturers Specifications
Shelf Life	24months----(2-8°C) Stability studies for 27months at 2-8 °C are submitted.
Document Details	**COPP (Original Legalized):** Certificate of veterinary pharmaceutical product having following information on it: **Composition**: The vaccine contains inactivated Newcastle disease virus A VII strain $\geq 10^8$ EID_{50}/0.1ml before inactivation. Product is licensed to be used in exporting country and manufacturer comply with veterinary medicine GMP. **Certifying authority**: Veterinary Bureau of Agriculture and Rural affairs Department of Jiangsu Province. **Stamp and date:** 11/02/2022 **Sole Agency Agreement:** **China Animal Husbandry industry vs Vet line international.** and a letter of statement affirming that Nanjing Bio-Pharmaceutical Factory of QYH Biotech Company Limited is a subordinate factory of QYH Biotech Company Limited. Nanjing Bio-Pharmaceutical Factory Is responsible to manufacture products only,. All the products are registered, commercialized, sold and distributed by QYH Biotech Company Limited. QYH Biotech Company Limited is also the firm under China Animal Husbandry Industry Co., Ltd (CAHIC) and CAHIC is the control shareholder of QYH. CAHIC is responsible for the export of QYH's products and for receiving the related payments.
Pack size	500ml/bottle
Reference Regulatory Authority Availability	N/A
Products already registered in Pakistan	Could not be confirmed
Remarks of Evaluator	Applied formulation is present in European Pharmacopoeia.
Previous Decision (M-316)	*Registration Board deferred the product for expert opinion of Dr. Qurban Ali, member Registration Board regarding immunological relevance of applied strain to Pakistan.*

Evaluation by DBER:

Now the expert opinion of Dr. Qurban Ali, member Registration Board has been received wherein he has recommended for registration the inactivated ND vaccine A-VII Strain from M/s Nanjing Biopharmaceutical, Jiangsu, China for use in Pakistan to minimize the genotype VII outbreaks in poultry birds and its consequent losses.

Expert opinion by Dr. Qurban Ali, Member Registration Board is as under:

Newcastle Disease (ND) is an important disease of poultry causing devastating losses, where disease control presents significant challenge to the poultry industry worldwide. ND is member of transboundary animal diseases (TADs) list of OIE, signifying it a most contagious and infectious disease of economic significance. Therefore, efforts to control ND anywhere aims at active immunization using combinations of live and killed virus vaccines to reduce (i) clinical signs, (ii) reduce virus shedding and (iii) protecting birds from the virus causing the disease.

NDV genome is non-segmented, single stranded RNA; where strains are classified as highly virulent (valogenic), intermediate (mesogenic) and non-virulent (lentogenic) pathotypes depending on their pathogenicity to chickens. Apart from pathotypes, NDVs could also be grouped into different genotypes based on genomic sequence and phylogenetic analysis of F gene. Majority of current ND

vaccines are live or inactivated genotype I and/or II NDVs, while virulent NDVs are grouped into genotype III to X. In 1990s two novel NDV genotypes VII and VIII were reported in Asia, South Africa and several European countries. Studies indicated presence of genotype VII with sub-genotypes (e, b and f) in Pakistan since 2011. Although intensive vaccination program runs in Pakistan, genotype VII outbreaks do occur sporadically even on vaccinated farms. Immunological studies elsewhere have shown that the genotype-matched vaccines provide better protection against challenge with the virulent genotype VII NDV and significantly reduce virus shedding compared to LaSota vaccine. Keeping in view the afore said, we may register the inactivated ND vaccine A-VII Strain from M/s Nanjing Biopharmaceutical, Jiangsu, China for use in Pakistan to minimize the genotype VII outbreaks in poultry birds and its consequent losses. ----- Sd ---- Dr. Qurban Ali Member Drug Registration Board
Decision: Keeping in view the legalized GMP, legalized FSC indicating product availability in country of origin, recommendation of veterinary expert; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Case No.17 Imported Veterinary Biological applied by M/s Snam Pharma, Lahore deferred in 316th meeting of Registration Board.

Name and address of Importer	**M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore**
Detail of DSL	M/s Snam Pharma, Address: 61-Block G, Phase-I, DHA, Lahore Cannt, District Lahore. Valid till: 14 November, 2022.
Name and address of Manufacturer	M/s Sante Animale Lot 157, zone industrielle Sud
Name of exporting country	Morroco
Brand Name +Dosage Form + Strength	Bovivax LSD-N Vaccine (50 doses)
Diary No. Date of R& I & fee	Dy. No. 8315R&I Dated 30-03-2022 Rs. 75,000/- (Slip No. 10439736)
Composition	**Lyophilizate:** Each dose contains: Attenuated live LSD virus, Neethling strain $\geq 10^{3.5}$ $TCID_{50}$ **Solvent:** Calcium chloride dihydrate… 0.132mg Disodium phosphate dihydrate…1.441mg Sodium chloride…8mg Potassium chloride….0.2mg Monopotassium phosphate…0.2mg Magnesium chloride….0.1mg Water for Injection ….s.q.f…1ml
Pharmacological Group	Vaccine
Type of Form	Form-5A
Finished Product Specification	Manufacturer's specifications
Shelf Life	24months (2^0C-8^0C) Stability studies of three batches at (2^0C-8^0C) for 30months.
Document Details	Copy of FSC for Bovivax LSD -N lyophilizate and copy of FSC for MCI solvent. Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively. For GMP of manufacturer firm has referred to Eudra GMP Certificate No. 118/2020/GMP. Which is verifiable from the site.
Pack size	50 doses 50ml solvent

Reference Regulatory Authority Availability	N/A
Products already registered in Pakistan	Mevac LSD of Bromed
Remarks of Evaluator	In response to this division's letter firm has submitted following: i. Notarized copy of product specific sole agency agreement. ii. Stability studies of diluent for 20ml and 200ml bottles is submitted. For FSC indicating diluent firm has submitted following: a. Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively in Morocco. b. Copy of registration license of biological product for Bovivax LSD-N with following pack vial 10 doses+20ml diluent, 25doses+50ml diluent, 50doses+100ml diluent and 100doses+200ml diluent (MCI sterile diluent) in Egypt. Document still required: i. FSC indicating free sale status of product in country of origin.
Previous Decision (M-317)	*Registration Board deferred the product for submission of valid legalized Free Sale Certificate indicating product availability in country of origin.*
Evaluation by DBER	*Firm has submitted original legalized FSC which does not indicate product availability in country of origin.*
Decision: Registration Board deferred the case for submission of evidence of approval of applied product in other countries including reference regulatory authorities.	
Name and address of Importer	**M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore**
Detail of DSL	M/s Snam Pharma, Address: 61-Block G, Phase-I, DHA, Lahore Cannt, District Lahore. Valid till: 14 November, 2022.
Name and address of Manufacturer	M/s Sante Animale Lot 157, zone industrielle Sud-Ouest B.P.278- C.P 28 810 Mohammedia-Morocco.
Name of exporting country	Morocco.
Brand Name +Dosage Form + Strength	Bovivax LSD-N Vaccine (10 doses)
Diary No. Date of R& I & fee	Dy. No. 9929R&I Dated 19-04-2022 Rs. 75,000/- (Slip No. 6035676445)
Composition	**Lyophilizate:** Each dose contains: Attenuated live LSD virus, Neethling strain $\geq 10^{3.5}$ $TCID_{50}$ **Solvent:** Calcium chloride dihydrate… 0.132mg Disodium phosphate dihydrate…1.441mg Sodium chloride…8mg Potassium chloride….0.2mg Monopotassium phosphate…0.2mg Magnesium chloride….0.1mg Water for Injection …s.q.f…1ml
Pharmacological Group	Vaccine
Type of Form	Form-5A
Finished Product Specification	Manufacturer's specifications
Shelf Life	24months (2^0C-8^0C) Stability studies of three batches at (2^0C-8^0C) for 30months.
Document Details	Copy of FSC for Bovivax LSD -N lyophilizate and copy of FSC for MCI solvent.

	Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively in Morocco. Copy of registration license of biological product for Bovivax LSD-N with following pack vial 10 doses+20ml diluent, 25doses+50ml diluent, 50doses+100ml diluent and 100doses+200ml diluent (MCI sterile diluent) in Egypt. For GMP of manufacturer firm has referred to Eudra GMP Certificate No. 118/2020/GMP. Which is verifiable from the site.
Pack size	10 doses 20ml solvent
Reference Regulatory Authority Availability	N/A
Products already registered in Pakistan	Mevac LSD of Bromed
Remarks of Evaluator	In response to this division's letter firm has submitted following: i. Notarized copy of product specific sole agency agreement. ii. Stability studies of diluent for 20ml and 200ml bottles is submitted. For FSC indicating diluent firm has submitted following: c. Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively in Morocco. d. Copy of registration license of biological product for Bovivax LSD-N with following pack vial 10 doses+20ml diluent, 25doses+50ml diluent, 50doses+100ml diluent and 100doses+200ml diluent (MCI sterile diluent) in Egypt. Document still required: i. FSC indicating free sale status of product in country of origin.
Previous Decision (M-317)	*Registration Board deferred the product for submission of valid legalized Free Sale Certificate indicating product availability in country of origin.*
Evaluation by DBER	*Firm has submitted original legalized FSC which does not indicate product availability in country of origin.*
Decision: Registration Board deferred the case for submission of evidence of approval of applied product in other countries including reference regulatory authorities.	

Cases of AD-IV (Muhammad Kashif)

A. Imported Human Biologicals from Non-Reference Countries:

18.	**Name of Importer**	M/s Amson Vaccines & Pharma (Pvt.) Ltd. Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
	DSL details	License No: 920-ICT/2013 **Address** Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad. Validity: 26-09-2022
	Name of Manufacturer	M/s Panacea Biotec Limited (Vaccine Division) Malpur, Baddi, Distt: Solan (HP)-173205, India
	Brand Name +Dosage Form + Strength	**EasySix vaccine**
	Composition	Each 0.5 ml dose contains: Diphtheria Toxoid...: ≥ 30IU Tetanus Toxoid-------≥60IU Inactivated Whole cell Pertusis-------≥4 IU R Hepatitis B surface antigen---------≥10 µg

		Haemophilus Influenzae Type b conjugated (PRP-TT) …. 10 µg Inactivated Salk Polio Virus Type 1---40DU Inactivated Salk Polio Virus Type 2---8 DU Inactivated Salk Polio Virus Type 3---32DU
	Finished product specifications	B.P Specifications
	Pharmacological Group	Human Vaccine
	Shelf life	24 months (2°C-8°C)
	Products already registered in Pakistan	Infanrix Hexa vaccine Reg. No. 028422 gsk
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No.23589 Dated 09-07-2018, Rs. 100,000/- dated 09-07-2018
	Packsize:	1's PFS/ As per SRO
	International Availability	Sanofi's pediatric hexavalent vaccine approved by U.S. FDA
	General documentation	***Original Legalized CoPP*** No. M2011076***:*** **Issued by:** State Drugs Controller Baddi Distt Solan India **Valid upto :**28-09-2022. ***Original Legalized GMP Certificate:*** • **Issued by:** As mentioned above **Valid upto :**28-09-2022.
	Remarks	**1. The product is human vaccine will be Imported from india and is not WHO PQ. However as per import Polcy order 2020 all the therapeutic goods from India are importable.** **2. The firm has submitted the stability data of clinical trial batches.**
Decision: The registration Board deferred the case for following points: **a. submission of real time stability study data on three commercial scale batches up the demanded shelf life.** **b. Refrred to DRAP Authority for decision regarding the importability of the product from India being non-WHO PQ product.**		

Case No. 19 EXEMPTION OF DRUG (LABELLING AND PACKAGING) RULES, 1986 AND PERMISSION FOR LOCAL PRINTING OF LABELLING PARTICULARS ON OUTER BOX ON IMPORT OF REGISTERED BIOLOGICAL PRODUCTS.

M/s Novartis Pharma (Pakistan) has applied for exemption of two of their biological products i.e., Simulect 20mg Injection (Reg. # 025218) and Xolair 150mg Powder for Solution for Injection (Reg. # 047599). The firm states that these products have very specific and limited usage in Pakistan and due to the production constraints. They are unable to supply these imported products in the country specific packs in low volumes.

Novartis Pharma (Pakistan) Limited wants for exemption of drug (labelling and packaging) rules, 1986 and permission for local printing of labelling particulars of the **following components** on **outer box** of imported products at their licensed premises situated at C-21, S.I.T.E Area, Karachi-75700 (DML # 000003) before sale/release into the market in compliance to Drug (Labeling and Packaging) Rules, 1986:

- Urdu Text
- Registration Number
- Maximum Retail Price
- Name and Address of the sole agent
- Other Information (as per labelling requirements)

The firm has submitted following documents:

a) Application.
b) Total Fee of Rs. 20,000/- (Rs. 10,000 each).
c) Copy of registration letters along with renewal letters.

d) Copy of valid DML # 000003.

Decision: Registration Board acceded to the request of the firm for import of Simulect 20mg Injection (Reg. # 025218) and Xolair 150mg Powder for Solution for Injection (Reg. # 047599) in Standard Export Packs. The Board advised the firm to locally print Urdu version, MRP, Registration Number and other parameters as per Drugs (Labelling & Packing) Rules, 1986 before sale of drug at M/s Novartis Pharma (Pakistan), C-21, S.I.T.E Area, Karachi-75700 (DML # 000003). This permission shall be valid for two (02) years only. The firm shall submit the future plan regarding the import of products in compliance with Drugs (Labelling & Packing) Rules, 1986.

Case No. 20. Request for incorporation of additional changes in renewal of registration certificate for polyvalent anti snake venum serum/Immunoglobulins.

M/s National Institute for Health, Islamabad (NIH) has applied vide letter No. NIH-ISB-CBPD/69/Reg/2022 dated Nill from Ghazala Parveen Chief Biological Production division, NIH, Islamabad. M/s NIH states as under:

"This is with reference to DRAP's letter F-9-33/2022 AD(BD)(PRV)(M-318) dated 7th July 2022 on above subject. Please find enclosed herewith the copy for your ready reference at (Flag-A). Sera lab is under process of product sample testing for independent product Risk assessment by WHO. In this regard samples along with relevant documentation has to be submitted to NCLB for release at the earliest.
In this regard the essential product information for renewal of registration of drugs under drugs act 1976 and rules framed thereunder is required by NCLB on registration renewal letter/certificate.

Registra-tion number	Product name name/brand name	Composition	Packing	Storage conditions & shelf life	Maximum retail price.
003846	Polyvalent Snake Antivenom immunoglobulins	Liquid Purified Equine Immunoglobulins	10ml vial	+2 to 8 ℃	
	B.P specifications	Each 1ml of Antivenom neutralizes not less than 3LD50 challenge venom dose of following snakes: 1.Russell's viper (*Daboia russellii*) 2.Pakistani Cobra species (*Naja naja*) 3. Common krait (*Bungarus caeruleus*) 4.Saw-scale viper (*Echis carinatus*).		2 years from date of manufacturing.	Current Price Rs.1651.46/- As per SRO.

Case History:

Proceedings of 318th Registration Board Meeting:

M/s NIH Islamabad vide letter dated 09th June 2022 & 5th July, 2022 has requested for issuance of duplicate registration certificate including changes incorporated for Polyvalent Anti-Snake Venom Serum (003846). The firm has requested for standardized formulation & description of container closure to submit the same to National Control Laboratory for Biologicals for lot release and the same certificate will assist NIH for making correspondence with WHO and other international agencies for collaboration and Joint Ventures; for this NIH has submitted revised label having following standardized formulation and requested for approval of the same. The firm M/s NIH, Islamabad verified that, as per WHO newly published guidelines 2010 & 2016, both descriptions as per their initial registration letter and requested standardized formulation for potency are equally acceptable.

Reg. No.	Product Name	Description of container closure
003846	Polyvalent Anti-Snake Venom Each ml neutralizes: 0.6mg of Russel's Viper (Daboia russelii) venom 0.6mg of Balck Cobra (Naja naja) venom 0.45mg of saw Scaled Viper (Echis carinatus) venom 0.45m of Common Krait Bun arus caeruleus venom	USP Type I Glass Vial of 10ml

It is submitted that National Institute of Health (NIH) Islamabad was granted registration of Polyvalent Anti-Snake Venom Serum as per following details:

Reg. No.	Product Name of Product	Description	Date of Registration	Renewal trail
003846	Polyvalent Anti-Snake Venom	Each ml of anti-snake venom serum neutralizes 2LDso of Cobra, Russell's viper, Krait, and Echis venom 10ml vial	April, 1977	• Renewal granted by erstwhile MOH vide letter No. F.3-3/2004-Reg-11 (M-184) dated 02.09.2004. • Renewal granted by erstwhile MOH vide letter No. F.11-19/2007-RRR dated 16.09.2008 valid till 02.09.2014 • Renewal for year 2014 was submitted on 26.08.2014, which is within time w.r.t approval dated 02.09.2004. • Renewal for the year 2019 was submitted on 17.09.2019 which is after due date but within sixty days. This requires submission of differential fee and Regularization by the Reg Board.

Keeping in view above it is submitted that the last renewal of the product was submitted on 17.09.2019, which is sixteen days late after due date, but within sixty days. Under Rule 27 of the Drugs {LRA) Rules, 1976 under Drugs Act, 1976 late renewals (within Sixty days) require regularization by Registration Board. The firm Mis NIH, Islamabad in this regard has deposited the requisite fee Rs. 10,000/- vide challan No. 9543242776 dated 06.07.2022.

The case is placed before the Registration Board for

i. Consideration of regularization of renewal of registration for product Polyvalent Anti-Snake Venom Serum (003846) ofM/s NIH, Islamabad.

ii. The renewal letter may be issued to the firm with revised nomenclature formulation as mentioned per details given below.

Decision of 318th meeting of RB:

Keeping in view position narrated above, Registration Board regularized the registration of above product w.e.f. 01-09-2019 to 31-08-2024 and advised DBE&R to issue renewal letter with following formulation and container closure description:

Reg. No.	Product Name	Description of container closure
003846	Polyvalent Anti-Snake Venom Each ml neutralizes: 0.6mg of Russel's Viper (Daboia russelii) venom 0.6mg of Black Cobra (Naja naja) venom 0.45mg of saw Scaled Viper (Echis carinatus) venom 0.45mg of Common Krait (Bungarus caeruleus) venom BP Specifications	USP Type I Glass Vial of 10ml

It was further decided to issue above letter today without waiting for the minutes as the lot release is pending at NCLB due to this regularization.

Accordingly, Renewal of Registration Letter No. 9-33/2022-AD(BD)(PRV)(M-318) dated 07-07-2022 was issued.

The evaluation is tabulated as under;

S. No	Reg. No.	Current parameters as per 318th R.B Meeting	Demanded parameters	Remarks of evaluators/Documents required as per approved SOPs
1.	003846	Polyvalent Anti Snake venom	Polyvalent Snake Antivenom immunoglobulins	**a) Application with required fee as per relevant SRO (in case of similarity / resemblance with drug, fee will not be required).** **b) Copy of registration letter and last renewal status.** **c) Justification for proposed change.** **d) Information regarding previous change of brand name since registration of drug.** **e) Details (batch number, date of manufacture, quantity and stock position) regarding last batch imported.** **f) An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance/similarity with already registered drug, the applicant will be liable to change**

				immediately. Moreover, no case is pending at any forum / court of law regarding this matter. **g) Original and legalized Certificate of Pharmaceutical Product as per WHO format for new brand name OR Original and legalized GMP certificate of new brand name with free sale certificate from regulatory body of country of origin.** **h) Undertaking that the provided information/ documents are true/ correct.**
2.		Nill	2 years from date of manufacturing.	**a) Application with required fee as per relevant SRO.** **b) Copy of registration letter and last renewal status.** **c) Proposed shelf-life, justification & data of long-term stability testing (as per conditions of zone IV-A) including chromatograms for a minimum of 3 commercial scale batches or development scale batches upto the proposed shelf-life.** **d) Approval of regulatory body of country of origin or Original and legalized Certificate of Pharmaceutical Product as per WHO format.** **e) Undertaking that:** **i. Provided information is true & correct.**
3.		Nill	(+2 to 8 ℃)	**a) Application with required fee as per relevant SRO.** **b) Copy of registration letter and last renewal status.** **c) Undertaking that:** **i. The change is in accordance with innovator's product/ Reference Regulatory Authorities** **ii. Provided information is true & correct.** **iii. The change is not necessitated by failure to meet specifications or resulting from unexpected events arising during manufacture.** **iv. If the change is necessitated because of stability concerns, declaration of reason for change in storage condition.**
4.		USP Type-I Glass vial of 10ml	10ml vial	**Clarification is required regarding inclusion of 10ml vial instead of USP Type-I Glass vial of 10ml.**
5.		Each 1ml neutralizes: 0.6mg of Russel's viper (Daboia russellii) venom 0.6mg of Black Cobra (Naja naja) venom 0.45mg of saw Scale Viper (Echis carinatus) venom 0.45mg of Common krait (Bungarus caeruleus) venom	Liquid Purified Equine Immunoglobulins. Each 1ml of Antivenom neutralizes not less than 3LD50 challenge venom dose of following snakes: 1.Russell's viper (*Daboia russellii*) 2.Pakistani Cobra species (*Naja naja*) 3. Common krait (*Bungarus caeruleus*) 4.Saw-scale viper (*Echis carinatus*).	**1. Clarification/justification is required regarding $3LD_{50}$ as in 318th R.B $2LD_{50}$ has already been changed to the current composition if the composition is changed the firm will have to apply for new registration.** **2. Clarification is also required for inclusion of "Liquid Purified Equine Immunoglobulins and Pakistani Cobra" in composition in any reference country and also any compendial reference**

As per direction of the Chairman Registration Board the case is placed for deliberation before the Registration Board.

Decision: Registration Board deferred the case for clarification from the applicant regarding the demanded parameters.

Case No. 21. <u>Deferred of M/s M/s Amson Vaccines & Pharma (Pvt.) Ltd deferred in 317th Registration Board meeting:</u>

21.	**Name, address of Applicant / Importer**	**M/s Amson Vaccines & Pharma (Pvt.) Ltd., Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.**
	Details of Drug Sale License of importer	License No: 920-ICT/2013 Address Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad. Validity: 01-08-2022
	Name and address of marketing authorization holder (abroad)	M/s Green Cross Corporation, 40 Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Republic of Korea
	Name, address of manufacturer(s)	M/s Green Cross Corporation, 40 Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Republic of Korea
	Name of exporting country	Republic of Korea
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	• Firm has submitted Legalized CoPP (No. 2021-A1-0638) dated 12-04-2022 issued by Ministry of Food and Drug Safety, Korea. The COPP specifies that the product is licensed for sale but not available in country of origin. The COPP also specifies the GMP ststua of manufacturer. • Firm has submitted Legalized FSC (No. 2020-A1-0504) dated 24-03-2022 issued by Ministry of Food and Drug Safety, Korea. The FSC specifies that the product is permitted to be freely sold in country of origin. • Firm has submitted legalized GMP certificate (No. 2021-F1-0184) dated 18-05-2021 valid till 25-02-2024 issued by Ministry of Food and Drug Safety, Korea.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized Sole Agency Certificate from General Manager of M/s Green Cross Corporation. According to the letter, the firm M/s Green Cross Corporation exclusively authorizes "M/s Amson Vaccines & Pharma (Pvt.) Ltd. for the purpose of registration, import, promotion and marketing of the product.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒Finished Pharmaceutical product import ☐Buk import and local repackaging ☐Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	32870 & 11223 Dated: 15-12-2021 & 10-05-2022
	Details of fee submitted	Rs: 150,000/- Dated: 11-11-2021 Deposit Slip No. 1882973539
	The proposed proprietary name / brand name	BARYCELA Inj.
	Strength / concentration of drug of Active	**Powder Vial:** Each vial contains:

	Pharmaceutical ingredient (API) per unit	Live attenuated varicella virus (strain: MAV/06, cell line : MRC-5)….≥3800PFU **Solvent Vial:** Each vial contains: Sterile Water for Injection…….0.7ml
	Dosage form of applied drug	Powder & Solvent for Intramuscular Injection
	Pharmacotherapeutic Group of (API)	Human Vaccine
	Reference to Finished product specifications	Not Provided
	Proposed Pack size	1's Vial (Powder) + 1's Vial (Solvent) 10's Vials (Powder) + 10's Vials (Solvent)
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	2 ˚C -8˚C
	The status in reference regulatory authorities	The firm has submitted Varivax as RRA status
	For generic drugs (me-too status)	Varicella vaccine with this strain is not registered.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Green Cross Corp., 586, Gwahaksaneop 2-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, South Korea
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Varicella vaccine bulk at real time conditions. The real time stability data is conducted at -80 ± 10˚C for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	Powder Vial: • Borosilicate (Type I) Glass Vial • Butyl Rubber Stopper • Aluminum cap

		Solvent Vial: • Borosilicate (EP Type I) Glass Vial • Chlorobutyl Rubber Stopper • Aluminum cap
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Barycela Inj. at accelerated and real time conditions. The real time stability data is conducted at 5 ± 3˚C for 24 months and accelerated stability is conducted at 25±2˚C for 06 months. Firm has submitted stability study data of 3 batches of Diluent at real time conditions. The real time stability data is conducted at 5 ± 3˚C for 36 months.
	Module-IV Non-Clinical	**Primary Pharmacodynamics** • Immune response comparison study by animal species (rabbit, rat, and guinea pig) • Efficacy comparison study in rabbits and guinea pigs • Efficacy comparison study with commercial vaccines in rabbits and guinea pigs • Preliminary local tolerance and efficacy study in rabbits **Repeat-dose Toxicity** • Repeated Subcutaneous Dose Toxicity Study of VZV Vaccine (MG1111) with a Recovery Period in Rabbits. **Other Toxicity Study** • A Neurovirulence Test of Attenuated Varicella-Zoster Virus (VZV) in Male Cynomolgus Monkeys
	Module-V Clinical	• A Single-center, Dose Block-randomized, Single-blind, Active-controlled, Dose Escalation Phase 1 Clinical Trial to Evaluate the Safety and Efficacy (Immunogenicity) of MG1111 in Healthy Adults • A Phase II/III, Single-blind (Stage 1), Double-blinded (Stage 2), Randomized, Active-controlled, Dose-escalation (Stage 1), Non-inferiority (Stage 2) Study to Evaluate Immunogenicity and Safety of MG1111 in Healthy Children
	Remarks of Evaluator	i. The submitted legalized **FSC** issued on **24-03-2022** specifies that the product is permitted to be freely sold in country of origin, however, legalized **CoPP** issued on **12-04-2022** indicates that the product is not actually available in the market in country of origin. ii. RRA status submitted by the firm is of OKA strain while the instant product has a different strain. iii. The instant strain is not registered in Pakistan. iv. pH is not tested in real time stability studies for which the firm has submitted that initially pH was not included in the studies and later Ministry of Food and Drug Safety, Korea (MFDS) advised them to include. The revised stability studies are not yet complete. v. Limits of virus concentration is different in Specifications (3800-38000PFU) and stability data (2530-25298PFU) for which the firm submitted that clinical trial was conducted with target virus concentration of 8000PFU but at the time of review by MFDS, the target virus concentration was 12000PFU, therefore, the final virus concentration limit is also changed from 2530-25298 PFU to 3800-38000PFU.

Decision: Registration Board deferred the product for submission of following by the firm:

i. Clarification regarding non-availability of product in country of origin as per submitted CoPP.
ii. Evidence of availability of Varicella vaccine with MAV/06 strain in Reference Regulatory Authorities.
iii. Immunological relevance of MAV/06 strain with circulating strains of Pakistan.
iv. Real time stability data including all parameters as per finished product specifications.

The firm has submitted following Documents and clarification:

i. New CoPP submitted by the firm shows the availability of the product in country of origin.
ii. The firm has submitted 28 days stress stability data of finished product with statement that after 02-03-2020.
iii. Regarding Immunological relevance of MAV/06 strain with circulating strains of Pakistan the firm has submitted

"Report on the Results of Immunogenic Cross-Reactivity Assessment on Attenuated Vaccine Strain and Wild-Type Varicella Viruses in the Serum of Children Administered Varicella Vaccines"

Conclusion of the study:

"-The serum samples of the MG1111 vaccination group did not show any statistically significant difference in the antibody titers analyzed with the FAMA antigens of 6 VZV strains regardless of clades or attenuation.

- *The serum samples of the Varivax vaccination group showed a statistically significant difference in the antibody titers analyzed with the FAMA antigens of 6 VZV strains. Specifically, when MAV06 and Jena 26 were used as antigens, the antibody titer was statistically significantly lower than the values measured using Varivax_Oka or YC03 as antigens.*
- *When FAMA analysis was performed with the same strain for 6 FAMA antigen strains, there was no difference in antibody titers between the MG1111 and Varivax vaccination groups.*

iv. Evidence of availability of Varicella vaccine with MAV/06 strain in Reference Regulatory Authorities is not provided.

Decision: Registration Board deferred the case for seeking expert opinion from EPI regarding immunological relevance and need of applied strains / vaccine for use in Pakistani population.

Item No. IV. Division of Quality Assurance & Laboratory Testing

S. No.	Case title
AGENDA ITEM NO. 01 - PERSONAL HEARING CASES	
01	MANUFACTURE & SALE OF MISBRANDED DEX-NEO CREAM REG. NO. 067664, BATCH NO. 299 MANUFACTURED BY M/S. ZANCTOK PHARMACEUTICAL LABS, HYDERABAD
02	MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD STERILE WATER FOR INJECTION REG. NO. 000040, BATCH NO. 799 MANUFACTURED BY M/S. ZAFA PHARMACEUTICAL LABORATORIES (PVT.) LTD., KARACHI
03	MANUFACTURE & SALE OF ADULTERATED & SUBSTANDARD ABEX INJECTION, REG. NO. 086072, BATCH NO. 21AL2, MFG. DATE 02-21, EXP. DATE 02-23, MANUFACTURED BY M/S. SEMOS PHARMACEUTICALS (PVT.) LTD., KARACHI
04	MANUFACTURE & SALE OF SUB-STANDARD INDOBID CAPSULE, REG. NO. 007106, BATCH NO. 386, MANUFACTURED BY M/S ADAMJEE PHARMACEUTICALS (PVT) LTD., KARACHI
05	MANUFACTURE & SALE OF SUB-STANDARD WATER FOR INJECTION, BATCH NO. LI-961 MANUFACTURED BY M/S. SAFE PHARMACEUTICAL PAKISTAN LTD. KARACHI.
06	MANUFACTURE & SALE OF SUBSTANDARD CIPRACEPT 250MG TABLET, REG. NO. 096357, BATCH NO. TCA-103, MFG. DATE 01-2021, EXP. DATE 01-2023, MANUFACTURED BY M/S. MISSION PHARMACEUTICALS, KARACHI
07	MANUFACTURE & SALE OF SUB-STANDARD DIAGYL SUSPENSION, BATCH NO. 162 BY M/S SWISS PHARMACEUTICALS (PVT) LTD, KARACHI. SURPRISED "INSPECTION OF M/S SWISS PHARMACEUTICALS PVT LTD, A -159, SITE SUPER HIGHWAY KARACHI STOCK ORDER NOT TO DISPOSE OF ON FORM-I
08	NON-SUBMISSION OF METHOD OF TESTING OF SASTALKA LIQUID BY M/S. SWAT PHARMACEUTICALS, SAIDU SHARIF SWAT
09	STOCKS OF DRUGS SEIZED UNDER SECTION 18 (1) OF THE DRUGS ACT, 1976 - M/S, PAK RISEN PHARMACEUTICALS, HATTAR
AGENDA ITEM NO. 02 - APPELLATE TESTING CASES	
10	MANUFACTURE & SALE OF SUB-STANDARD PANTOLOON TABLET, REG. NO. 095091, BATCH NO. 5602 MANUFACTURED BY M/S. ROCK PHARMACEUTICAL LABORATORIES (PVT) LTD., RISALPUR.
11	MANUFACTURE & SALE OF SUB-STANDARD BIOFEN SUSPENSION, REG. NO. 046094, BATCH NO. SP-167, MANUFACTURED BY M/S. BIO-LABS PRIVATE LIMITED, ISLAMABAD.
12	MANUFACTURE & SALE OF SUB-STANDARD MAPARIX INFUSION, REG. NO. 050695, BATCH NO. L-21019 MANUFACTURED BY M/S. S.J.&G. FAZUL ELLAHIE (PVT.) LTD., KARACHI.
13	SUBSTANDARD 25% DEXTROSE INFUSION B. NO. A042C21 MANUFACTURED BY M/S. OTSUKA PAKISTAN LTD., HUB, BALOCHISTAN
14	SUBSTANDARD NYLOZ CAPSULE MANUFACTURED BY M/S. ZEPHYR PHARMATEC (PVT) LTD. KARACHI
15	SUBSTANDARD DELMOL SUSPENSION MANUFACTURED BY M/S. DELTA PHARMA (PVT.) LTD., NOWSHERA
AGENDA ITEM NO. 03 - ROUTINE CASES	
16	MANUFACTURE & SALE OF SUBSTANDARD KLEVRA ORAL SOLUTION, REG. NO. 066831, BATCH NO. 0N152, MFG. DATE DEC. 2020, EXP. DATE DEC. 2022, MANUFACTURED BY M/S. PHARMEVO (PVT.) LTD. KARACHI
17	MANUFACTURE & SALE OF SUB-STANDARD MELOVETZ INJECTION, REG. NO. 102021, BATCH NO. 2199017 MANUFACTURED BY M/S. VETZ PHAARMACEUTICALS (PVT.) LTD., KOTRI
18	NON-SUBMISSION OF METHOD OF TESTING OF IPOMALT-F TABLETS BY M/S. ROCK PHARMACEUTICAL PVT LTD RISALPUR
19	NON-SUBMISSION OF METHOD OF TESTING OF WELOMEP INFUSION BY M/S. WELWRD PHARMACEUTICALS, HATTAR
20	NON-SUBMISSION OF METHOD OF TESTING OF REMEP INJECTION BY M/S. AULTON PHARMACEUTICALS, HATTAR
21	MANUFACTURE & SALE OF SUB-STANDARD TEMPRIN TABLETS, BATCH NO. 055, MANUFACTURED BY M/S KOHS PHARMACEUTICAL (PVT.) LTD., HYDERABAD
22	CASE REFERED BY PQCB, PUNJAB REGARDING REGULATORY METHOD OF ANALYSIS OF HEMOROSE-F TABLETS SUBMITTED BY M/S NEOMEDIX PHARMA
23	NOT TO DISPOSE OF UNDER SECTION 18(1)(I) OF DRUGS ACT, 1976 – M/S. HAWK BIO PHARMACEUTICALS PVT LTD, PLOT NO.10, STREET NO. S-6, NATIONAL INDUSTRIAL ESTATE, RCCI RAWAT

24	IMPORT OF REGISTERED PRODUCTS THROUGH FAKE/FORGED INVOICES BY M/S. BIOCURE PHARMACEUTICALS, LAHORE
25	ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S. EG PHARMCEUTICALS 13-A INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD
26	CLUSTER OF SERIOUS ADRS REPORT BY USE OF VISO-REM (REMDESIVIR) INFUSION MFG BY M/S. GLOBAL PHARAMCEUTICALS ISLAMABAD IN BAHRIA HOSPITAL LAHORE
27	CANCELLATION/SUSPENSION OF REGISTRATION OF WATER FOR INJECTION 2ml (REGISTRATION NO. Q24873) MANUFACTURED BY M/S AMSON VACCINES PHARMA (PVT) LTD, PLOT #154, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD
AGENDA ITEM NO. 04 - CASES REFERED BY QCB ISLAMABAD	
28	SUBSTANDARD GENTAMYCIN EAR DROPS MANUFACTURED BY M/S. AMROS PHARMA KARACHI – QCB ISLAMABAD CASE
29	SUBSTANDARD MULTIVITAMIN SYRUP B. NO. J19:018 MANUFACTURED BY M/S. NAWABSONS LABORATORIES, JIA BAGGA OFF RAIWIND ROAD, LAHORE – QCB ISLAMABAD CASE
30	SUBSTANDARD MENTIN FORTE TABLET MANUFACTURED BY M/S. UNEXO LABS LAHORE – QCB ISLAMABAD CASE
31	MISBRANDED BALINGO INJECTION B. NO. BL-1417 MANUFACTURED BY M/S. BAJWA PHARMACEUTICALS (PVT.) LTD., 36-KM OFF G.T ROAD LAHORE – QCB ISLAMABAD CASE
32	SUBSTANDARD METRONIDAZOLE 400MG B. NO. 597 MANUFACTURED BY M/S. NAWABSONS LABORATORIES, JIA BAGGA OFF RAIWIND ROAD, LAHORE – QCB ISLAMABAD CASE
33	SAMPLES NOT TESTED DUE TO TECHNICAL CONSTRAINTS

AGENDA ITEM NO. 01
PERSONAL HEARING CASES

CASE No. 01: MANUFACTURE & SALE OF MISBRANDED DEX-NEO CREAM REG. NO. 067664, BATCH NO. 299 MANUFACTURED BY M/S. ZANCTOK PHARMACEUTICAL LABS, HYDERABAD.

The Federal Inspector of Drugs-IV, DRAP inspected the premises of M/s. Zanctok Pharmaceuticals Karachi dated 18-11-2021 and following sample of drug taken on Form-3 for the purpose of test/analysis. Details are:

S. No.	Product Name	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Remarks of CDL
01	Dex-Neo cream	M/s. Zanctok Pharmaceutical Labs, Hyderabad	067664	299	11-2021	10-2023	The inner most label (tube) does not contain date of expiry as required under rule 3 of the Drugs (labelling & Packing) Rules 1986. Hence, sample is declared **"Misbranded"** under the Drug Act, 1976.

The sealed sample of above drugs was sent by FID to Federal Government Analyst, Central Drugs Laboratory, Karachi for the test/analysis vide this office memorandum No. SHM-NTF-64-66/2021-FID(K)-IV dated 19-11-2021.
The sealed portion of sample was also sent by FID to Chairman, Drug Registration Board, DRAP, Islamabad vide office letter of even number dated 19-11-2021.
The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the sample as Misbranded under the Drugs Act, 1976, vide test report No.KQ.348/2021 dated 25-01-2022.
In the light of above test report of Federal Government Analyst, Central Drugs Laboratory, Karachi, FID issued an explanation letter of even number dated 31-01-2022 to M/s. Zanctok Pharmaceuticals Hyderabad to explain their position in the matter for manufacturing/selling of above-mentioned Misbranded drug.
M/s. Zanctok Pharmaceuticals Hyderabad explained their position vide letter dated 07-02-2022. The firm's stance was reproduced as:

> "Keeping in view all the above-mentioned facts, it is stated that we owe to rectify the improper labeling (i.e no expiry date mentioned on primary packaging which was missed during engraving labeling on tubes due to machine problem) of our product Dex-Neo cream from the very next following batch with immediate effect."

In light of FGA report, M/s Zanctok Pharmaceuticals Hyderabad involved in manufacturing and selling of Misbranded drug Dex Neo cream Batch no. 299 and violated section 23(1)(a)(iii) of the Drugs Act 1976 and rules framed under.
Further, FID recommended that action under section 42 of the Drugs Act, 1976.
Section 42 of the Drugs Act 1976 reproduced as:

> "Where any person has been found to have contravened any of the provisions of this Act or the rules in respect of any registered drug, the Registration Board may, after giving such person an opportunity of being heard, cancel the registration of such drug or suspend such registration for a specified period."

Decision of 316th Meeting of Registration Board.

> "The Board after thorough deliberations, considering the facts of the case, decided to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Zanctok Pharmaceuticals Hyderabad and called them for personal hearing before Registration Board."

Decision of 316th meeting of Registration Board has been communicated vide letter No. F.03-11/2022-QC (316-RB) dated 27-05-2022.
Firm has replied vide Ref No. ZPL/046/2022 dated 30-05-2022 where in firm agreed for personal hearing.
Firm has been called for Personal hearing.
Procedings and Decision of 320th Meeting of Registration Board.
M/s Zanctok Pharmaceutical Laboratories submitted vide Ref No. ZPL/117/2022 dated 30-08-2022 that:

> "[…] Unfortunately, we have received the above subject letter on 30-08-2022 in afternoon through Whats App. We still have not received the letter through Pakistan post/courier. We believe due to heavy rain and flood in Hyderabad, no post was received to the factory. Due to receiving of the letter in late hours (Last Day), we are not getting flight for tomorrow to Islamabad. Therefore, we request you to move the hearing date to next month […]"

Decision: *"The Board after considering the facts of the case, request of the firm to grant another opportunity of personal hearing and after thorough deliberations acceded the request and provide them another opportunity of personal hearing."*

In view of decision of 320th meeting, they have been called for personal hearing.
Proceedings and Decision of 321st Meeting of Registration Board.
Ms. Almas Saeed, QA Manager appeared before the Board on behalf of M/s Zanctok Pharmaceutical Laboratories Hyderabad. She admitted that they have rectified the problem and expiry date has been printed on the tubes.
Registration Board after detailed discussion and thorough deliberations decided as follows:

a. **to issue warning letter to the firm in the matter.**
b. **directed the firm to further improve / strengthen quality assurance system by hiring qualified persons and review existing processes by incorporating more quality checks. Report for aforementioned action shall be submitted to QA&LT Division within 1 month time for appraisal of Registration Board.**

CASE NO. 02: MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD STERILE WATER FOR INJECTION REG. NO. 000040, BATCH NO. 799

MANUFACTURED BY M/S. ZAFA PHARMACEUTICAL LABORATORIES (PVT.) LTD., KARACHI.

The Federal Inspector of Drug-III / Assistant Director-XII, DRAP, Karachi inspected the premises of M/s. National Institute of Child Health (NICH) Rafeeqi Shaheed Road Karachi. on 28-05-2021 wherein the sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3.
The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Adulterated and Sub-Standard" quality vide their test report No.KQ.134/2021 (Initial) dated 11th June 2021 and test report No. KQ.134/2021 (Final) dated 30th, July 2021.

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	Result of CDL	Basis of Result
01	Zafixime 500mg Injection	027228	440	01-2021	01-2023	M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi.	Standard	-
-	Strile Water for Injection 5ml Ampoule	030217	799	12-2020	12-2025	---do---	Adulterated & Substandard	**Containing white fibers visible to the naked eye.**

In the light of above test reports of Federal Government Analyst, Central Drug Laboratory, Karachi an explanation letter of even number dated 11th June 2021 and 02nd, August 2021 issued by FID to M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Plot No. B-10, Block-B, S.I.T.E. North Karachi, for explaining their position in the matter of manufacturing/selling of above mentioned Adulterated and Sub-Standard drug.
M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Plot No. L-1/B, block 22, Federal "B", Area Karachi, 75950 vide their letter No. Nil dated 23th August,2021 requesting for retesting of Drug Zafixime 500mg Injection Batch No. 440, from NIH Islamabad. under section 22(5) of the drug Act 1976 for testing.
FID submitted the request of firm for retesting dated 25-08-2021.
M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, again requested for Appellate testing dated 07-10-2021.
Proceedings and Decision of 313th Meeting of Registration Board.
The Board after thorough deliberations and considering the facts of the case decided to ask/request Federal Government Analyst, Karachi to provide OOS investigation and complete testing record on which the product is declared as of Adulterated and Substandard quality.
The decision of Board has been communicated dated 16-12-2022 after approval of minutes.
M/s. Zafa Laboratories replied dated 11-01-2022, the conclusion of firm is reproduced as:

"In light of above investigation, product Water for Injection 5ml, Batch no. 799 was found as per specification. Therefore, OOS is not required against complaint."

Response received from Central Drugs Laboratory, Karachi received through WhatsApp dated 14-03-2022 wherein the remarks of OOS Investigation Form are reproduced as:

"Containing white fibers (WFI) visible to the naked eyes. The sample is of adulterated and substandard quality.

Technical Evaluation of the case:

- Water for injection was declared adulterated and substandard, containing white fibers visible to the naked eyes.
- Defects may not be equally distributed over the batch that's why it is not necessary for a Board or retention portion to be defective. Allowing retesting may result in false negative results and pose the risk to patient which can be avoided otherwise.
- Moreover, the remarks of CDL may be considered for further investigation of quality defect considering the statistical validity of sample size.

Proceedings and Decision of 316th Meeting of Registration Board.
The Board after thorough deliberations and considering the facts of the case decided:

i. To issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Zafa Pharmaceutical Laboratories (Pvt.) Ltd., Karachi and called them for personal hearing before Registration Board.

Mr. Adnan Rizvi, Member of Board has recorded his note of dissent i.e. the sample should be sent to NIH for appellate testing.

Decision of 316th meeting of Registration Board has been communicated vide letter No. F.03-11/2022-QC (316-RB) dated 27-05-2022.

Firm has replied vide letter Nil dated 02-06-2022 wherein they again requested to send sample for appellate testing to NIH for physical testing.

Firm has been called for personal hearing.

Proceedings and Decision of 320th Meeting of Registration Board.

M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi submitted vide Ref No. Nil dated 29-08-2022 that the concerned technical person was not available to attend the hearing due to unavoidable circumstances (rain and flood). They further requested for personal hearing in next meeting.

Decision: "The Board after considering the facts of the case, request of the firm to grant another opportunity of personal hearing and after thorough deliberations acceded the request and provide them another opportunity of personal hearing."

In view of decision of 320th meeting, they have been called for personal hearing.

Procedings and Decision of 321st Meeting of Registration Board.

Mr. Aquil Ahmed Rizvi, QA Manager and Mr. Ikram Habib, Manager Regulatory appeared before the Board. They inform that they have tested the retained sample of product and found it satisfactory and request to send the Board's portion for Appellate testing.

Registration Board after detailed discussion and considering the facts of the case decided:

"Sample of Sterile Water for Injection Batch No. 799 manufactured by M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Plot No. B-10, Block-B, S.I.T.E. North Karachi will be sent to appellate lab for testing of visible particulate matter, on which the sample was declared as Adulterated and Substandard by CDL, Karachi."

CASE NO. 03: MANUFACTURE & SALE OF ADULTERATED & SUBSTANDARD ABEX INJECTION, REG. NO. 086072, BATCH NO. 21AL2, MFG. DATE 02-21, EXP. DATE 02-23, MANUFACTURED BY M/S. SEMOS PHARMACEUTICALS (PVT.) LTD., KARACHI.

FID, DRAP, Karachi inspected the premises of M/s. JPMC, (Central Pharmacy) Rafeeqi Shaheed Road Karachi. on 23-04-2021, wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3.

The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Adulterated and Sub-Standard" quality vide their test report No.KQ.100/2021 (Initial) and (Final) dated 26th May 2021 and 15th June 2021**.**

S. No.	Name of Drug	Reg. No	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Result of CDL	Basis of Result
01	Injection Abex	086072	21AL2	02/2021	02/2023	M/s. Semos Pharmaceuticals (Pvt) Ltd. Plot #11, Sector 121-A, North Karachi. Industrial Area, Karachi.	Adulterated & Sub-standard	**After reconstitution, containing black particles visible to naked eye.**
02	Ampoule of Water for Injection	026762	WF2-243C	JAN-2021	JAN-2026	M/s. Surge Labortories (Pvt) Ltd. 10th Km, Faisalabad Road, Bikhi, District Sheikhupura	Standard	-

In the light of above test report KQ.100/2021 (Initial) dated 26th May 2021 of Federal Government Analyst, Central Drug Laboratory, Karachi an explanation letter of even number dated 27th May 2021 and 17th June 2021 were accordingly issued to M/s. Semos Pharmaceuticals (Pvt) Ltd. Plot #11, Sector 121-A, North

Karachi. Industrial Area, Karachi. for explaining their position in the matter of manufacturing/selling of above mentioned Adulterated and Sub-Standard drug

M/s. Semos Pharmaceuticals (Pvt) Ltd. Plot #11, Sector 121-A, North Karachi. Industrial Area, Karachi vide their letter No. SP/L TR047 dated 28th June 2021 requesting for retesting of Drug Abex Injection Batch No. 21AL2 from NIH Islamabad.

FID stated that in the light of above, portion of sample lying with the Board may be got retested from Appellate Laboratory National Institute of Health (N.I.H) Islamabad.

Proceedings and Decision of 313th Meeting of Registration Board.

The Board after thorough deliberations and considering the facts of the case decided to ask/request Federal Government Analyst, Karachi to provide OOS investigation and complete testing record on which the product is declared as of Adulterated and Substandard quality.

The decision of Board has been communicated dated 16-12-2022 after approval of minutes.

M/s. Semos Pharmaceuticals, Pvt Ltd., Karachi dated 27-12-2021, the firm mentioned that they have checked retention samples and recall samples as described process but didn't see any particles after reconstitution.

Firm also highlighted the remarks of CDL report reproduced as:

- As per requirements of USP general chapter <790> additional units may be inspected (As per ANSI/ASQ Z 1.4 or ISO 2859-1 standard for sampling) to gain further information on the risk of particulates in the batch.
- It is also mentioned in USP <790> that because of complaint and regulatory concern inspect 20 units, but they have received 10 units only. That's why they have requested to inspect more samples as per CDL remarks.

For the greater public interest and precautionary measures, they revalidated the Cephalosporin sterile area after replacing the filters where necessary i.e. HEPA filters for tunnel sterilization etc and other HEPA filters were also re-validated where necessary. They conducted DOP test on the filters. They further requested for appellate testing under section 22(4) of the Drugs Act 1976.

Response received from Central Drugs Laboratory, Karachi dated 14-03-2022 wherein wherein the remarks of OOS Investigation Form are reproduced as : "Adulterated and Substandard".

Technical Evaluation of the case:

- Product is declared as adulterated and substandard after reconstitution, containing black particles visible to naked eyes.
- Firm has conducted risk assessment however the risks are defined by firm in low to moderate range. DOP test was also conducted but no remarks was mentioned in the report.
- Defects may not be equally distributed over the batch that's why it's not necessary for a Board portion or retention portion to be defective. Allowing retesting may result in false negative results and pose the risk to patient which can be avoided otherwise.
- Moreover, the remarks of CDL may be considered for further investigation of quality defect.

Decision of 316th Meeting of Registration Board.

The Board after thorough deliberations and considering the facts of the case decided:

i. To issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Semos Pharmaceuticals (Pvt.) Ltd., Karachi and called them for personal hearing before Registration Board

Mr. Adnan Rizvi, Member of Board has recorded his note of dissent i.e. the sample should be sent to NIH for appellate testing.

Decision of 316th meeting of Registration Board has been communicated vide letter No. F.03-11/2022-QC (316-RB) dated 27-05-2022.

Firm has replied vide Ref. No. SP/LTR/062 dated 01-06-2022 wherein they again requested to send sample for appellate testing to NIH for physical testing and ready to appear before the Board.

Firm has been called for personal hearing.

Proceedings and Decision of 320th Meeting of Registration Board.

M/s. Semos Pharmaceuticals, Pvt Ltd., Karachi submitted vide Ref No. SP-LTR/065 dated 31-08-2022 that their flight had been delayed at the last moment and no other flight was available in short span of time. They further requested for another date for personal hearing.

Decision: "The Board after considering the facts of the case, request of the firm to grant another opportunity of personal hearing and after thorough deliberations acceded the request and provide them another opportunity of personal hearing."

In view of decision of 320th meeting, they have been called for personal hearing.

Proceedings and Decision of 321st Meeting of Registration Board

Mr. Mutti-Ur-Rehman, Director and Mr. Waqas Kamil, QA Manager appeared before the Board. They inform that they have tested the retained sample of product and found it satisfactory and request to send the Board's portion for Appellate testing.

Registration Board after detailed discussion and considering the facts of the case decided:

"Sample of Abex Injection Batch No. 21AL2 M/s. manufactured by Semos Pharmaceuticals (Pvt.) Ltd., Karachi will be sent to appellate lab for testing of visible particulate matter on which the sample was declared as adulterated and substandard by CDL, Karachi."

Case No. 04: MANUFACTURE & SALE OF SUB-STANDARD INDOBID CAPSULE, REG. NO. 007106, BATCH NO. 386, MANUFACTURED BY M/S ADAMJEE PHARMACEUTICALS (PVT) LTD., KARACHI.

FID Karachi vide letter No. F.ARS-107-109/2021-FID-II (K) dated 02nd August 2021 wherein the FID Karachi has informed that the sample was received in CDL, Karachi wherein, the Federal Government Analyst has declared following samples of Indobid Capsule as of "Substandard quality".

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL Remarks
Indobid Capsule	M/s Adamjee Pharmaceuticals (Pvt) Ltd., Karachi	007106	386	01-2021	01-2025	Substadard on basis of Dissolution.

Results of CDL on the basis of which sample under reference has been declared as Sub-Standard quality are reproduced as under:-

S.No.	Test	Specification	Result	Reference
1	Description	Hard gelatin capsules consist of white body and blue coloured cap, containing off white powder.	Complies	Mfg. Specs.
2	Identification	The identification test must identify Indomethacin.	Complies	BP 2020
3	Dissolution	Each unit is not less than 70%	**Does not Comply.**	BP 2020
4	Assay Indomethacin (Lebel claim 25mg/ capsule)	90.0% to 110.0%	103.2%-Complies	BP 2020

Remarks: The sample is "Sub-Standard" quality under the Drugs Act, 1976.

The FID Karachi has further informed that the firm has sent the explanation letter to explain their position dated 13th July 2021 regarding the violation of Drug Act 1976 and DRAP Act 2012.

The firm has submitted their reply dated 30th July 2021, wherein they requesting for retesting of Drug Indobid Capsules B.No.386 from NIH Islamabad.

In light of Supreme Court judgement of "C.P.1692-L/2020, C.P.1792-L/2020 and C.P.5-L/2021" and firm's request for appellate testing, the case is submitted for consideration of Board.

Proceedings and Decision of 312th Meeting of Registration Board.

The case has been deferred till the finalization of Appellate Testing Guidance Document/Protocol.

The agenda of "Handling requests of Appellate Testing- Guidance document for registration Board" was discussed in 313th meeting of Registration Board. The Board after thorough deliberations and considering the facts of the case decided as:

i. The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.
ii. Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.
iii. Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case.

OOS investigation was asked by firm and CDL vide office letter dated 23-12-2021.

The firm submitted the response dated 16-02-2022. They provided the results of initial test, Keeping sample and warrantor portion and request for appellate testing. However, OOS investigation was not provided.

CDL submitted the response dated 15-03-2021 wherein they mentioned: OOS is validated.

Technical Evaluation of the case:

i. The product was declared substandard on dissolution.
ii. CDL performed the test as per BP 2020 while firm performed on manufacturer specs.
iii. Audit trail was not provided by firm.
iv. Data is not time stamped hence data integrity cannot be verified.

Proceedings and Decision of 317th Meeting of Registration Board:

Out of Specification (OOS) investigations and testing records submitted by M/s. Adamjee Pharmaceuticals (Pvt) Ltd., Karachi and CDL, DRAP Karachi was presented before Registration Board. The Board deliberated the case in detail as follows:

i. M/s. Adamjee Pharmaceuticals (Pvt) Ltd., Karachi requested for Appellate testing. In compliance to the decision of 313th meeting of Registration Board firm and CDL were asked to submit Out of specification (OOS) investigation vide office letter dated 23-12-2021. The firm submitted the response dated 16-02-2022. They provided the results of initial test, Keeping sample and warrantor portion and request for appellate testing. However, OOS investigation was not provided. While CDL submitted the response dated 15-03-2022 wherein they mentioned that OOS is validated.

ii. Review of documents revealed that the product "Indobid Capsule" (Reg# 007106) was registered vide letter No.F.3-4/83-Reg(M-51) dated 16-01-1984 and no specification was mentioned in registration letter. Later on the subject product was included in BP specifications Minutes of 317th meeting of Registration Board (16-17 May, 2022) | 877 while the firm is still manufacturing and testing the product per manufacturer specifications. Further in 197th meeting of Registration Board held on 3-4 th May 2006, the Board decided as:

"All the firms shall adopt the specifications mentioned in the official pharmacopoeias for all the formulation except those drugs not included in the official pharmacopoeias. For these drugs manufacturers may adopt their own specifications till the inclusion of that formulation in the official pharmacopoeias. after this decision firms will not be allowed to adopt their own specifications for the drugs, which are included in any of the official pharmacopoeias, listed in the Section 3 of Drugs Act, 1976."

Decision: Keeping in view position narrated above, the Board concluded that the firm is still manufacturing/testing the said product as per manufacturer specifications despite of the fact that it is included in the official pharmacopoeia (BP). Therefore, Board did not accede the firm's request of appellate testing. Thus, the Board decided to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Adamjee Pharmaceuticals (Pvt) Ltd., Karachi and called them for personal hearing before Registration Board.

Decision of 317th meeting of Registration Board has been communicated vide letter No. F.03-30/2022-QC (317-RB) dated 21-06-2022.

Firm has replied vide Ref. No. Nil dated 28-06-2022 wherein they mentioned that they are the only company in Pakistan manufacturing Indomethacin capsule. They further said that they already imported a huge quantity of the said product foil, therefore they will change it to official pharmacopeia after consumption of the present foil.

Firm has been called for personal hearing.

Procedings and Decision of 320th Meeting of Registration Board.

M/s. Adamjee Pharmaceuticals, Pvt Ltd., Karachi submitted vide Ref No. Nil dated 31-08-2022 that their flight had been delayed. They further requested for personal hearing in next meeting.

Decision: "The Board after considering the facts of the case, request of the firm to grant another opportunity of personal hearing and after thorough deliberations acceded the request and provide them another opportunity of personal hearing."

In view of decision of 320th meeting, they have been called for personal hearing.

Proceedings and Decision of 321st Meeting of Registration Board.

Mr. Asim Kamal Ansari, QC Manager appeared before the Board on behalf of M/s. Adamjee Pharmaceuticals, Pvt Ltd., Karachi. He reiterated the same stance submitted earlier that they have tested the retained sample of product and found it satisfactory and requested to send the Board's portion for Appellate testing.

Decision: Registration Board after considering the facts of the case and after thorough deliberations decided:

i. Immediate suspension of the registration of Indobid capsule (Registration No. 007106) for a period of six months from the date of communication of decision.

ii. Submission of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by the firm and its verification by following panel.

- **Mr.Abdur Rasool Shaikh, Additional Director, DRAP, Karachi.**

- **Mr.Affan Ali, Assistant Director, CDL, Karachi.**

iii. **Recommendations of panel will be placed before Registration Board for decision.**

Case No. 05: MANUFACTURE & SALE OF SUB-STANDARD WATER FOR INJECTION, BATCH NO. LI-961 MANUFACTURED BY M/S. SAFE PHARMACEUTICAL PAKISTAN LTD. KARACHI.

FID, DRAP, Karachi inspected M/s. Safe Pharmaceuticals Pvt Ltd., Karachi on 14-01-2022; wherein following sample of drugs along with other drugs were taken for the purpose of test/analysis on prescribed Form-3:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Result of CDL
Noran-40 Injection (vial)	M/s. Safe Pharmaceuticals Pvt Ltd., Karachi.	093293	LP-255	09-21	09-23	Standard
Water for injection (ampuole)	M/s. Safe Pharmaceuticals Pvt Ltd., Karachi.	020632	LI-961	03-21	03-24	Sub-Standard

FID sent sealed samples of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the test/analysis on Form-4 dated 14-01-2022.

The Government Analyst, Central Drugs Laboratory, Karachi vide test report No.KQ-1-22-000016 dated 28-02-2022 declared the sample of water for injection as **"Sub-Standard"** quality under the Drugs Act, 1976, which is violation of Section 23(1) (a) (v) of Drugs Act, 1976 and rules framed there under.

FID issued an explanation letter of even numbers dated 08-03-2022 and reminder dated 19-04-2022. No reply received.

FID recommended that:

1. Registration of product may be suspended/cancelled for a certain period.
2. PSI may be carried out by panel of inspectors
3. The names of technical persons may be obtained from Licensing Division DRAP Islamabad as firm did not provided the name.

FID-II Karachi vide letter No.F.000349/2018-FID-II (K) dated 26-05-2022 wherein he submitted names of technical persons and reply of M/s. Safe Pharma where firm challenged the test report of CDL and requested for retesting of sample.

It is observed that no date was mentioned on firm's letter, however, the diary No 999 of Karachi office and date 26-05-2022 mentioned on the letter. As per Section 22 (4) of Drugs Act 1976, the firm should apply within 30 days of the receipt of a copy of the report. The firm's request was not acceded.

Names of firm's representatives provided by FID have been verified by Licensing Division. Following are the names of responsible persons:

- Mr. Muhammad Farooq S/o M. Haji Ahmed CNIC No. 42201-0622163-1. – Partner
- M. Saleem S/o M. Haji Ahmed CNIC No. 42000-0524844-3 – Partner
- Mr. M. Asif Sheikhani S/o Ghulam M Sheikhani CNIC No. 42201-0622163-1 – Partner
- Mr. M. Ahmed Sheikhani S/o Ghulam M Sheikhani CNIC No. 42000-0524844-3 – Partner
- Ms. Sadia Saeed D/o Saeed Khan – QC In charge CNIC No. 42101-3430721-4
- Mr. M. Saeed Ahmed S/o Abdul Ghaffar– Production in charge CNIC No. 42101-7783898-9

A show cause notice has been served after approval dated 25-08-2022.

M/s. Safe Pharmaceuticals Pvt Ltd., Karachi replied vide letter: WFI/2022-08-31 dated 31-08-2022. They mentioned that

> *"[…] We have already requested to send water for injection for any third Appellate laboratory for further investigation of said batch. we are very confident to our product we checked it multiple time and we did not find any ambiguity related to BET test. we are very conscious in quality of product and still we did not receive any complain related to said batch. Further not only for said batch but in any batch of water for injection which we had manufactured and supplied since many years, did not find any ambiguity or any market complain […]."*

In light of show cause notice and firm's reply; they have been called for personal hearing.

Procedings and Decision of 321st Meeting of Registration Board.

Mr. Muhammad Shahid, Regulatory Manager appeared before the Board on behalf of M/s. Safe Pharmaceuticals Private Limited, Karachi. He submitted that technical persons were coming but their flight was delayed and requested to provide some time as they reached by 4:00 PM. The Board after discussion

allowed them to be appeared by 4 PM or ex-parte decision will be taken. No one appeared before the board till end of the meeting.

Decision: Registration Board after considering the facts of the case and after thorough deliberations decided:

i. **Immediate suspension of the registration of Water for injection (ampoule) (Registration No. 020632) for a period of six months from the date of communication of decision.**

ii. **Submission of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by the firm and its verification by following panel.**
- **Mr.Abdur Rasool Shaikh, Additional Director, DRAP, Karachi.**
- **Mr. Awais Ahmad, Assistant Director, CDL, Karachi.**

iii. **Recommendations of panel will be placed before Registration Board for decision.**

Case No. 06: MANUFACTURE & SALE OF SUBSTANDARD CIPRACEPT 250MG TABLET, REG. NO. 096357, BATCH NO. TCA-103, MFG. DATE 01-2021, EXP. DATE 01-2023, MANUFACTURED BY M/S. MISSION PHARMACEUTICALS, KARACHI.

FID, DRAP, Karachi inspected M/s. Mission Pharmaceuticals (Pvt.) Ltd., A-94, SITE Super Highway, Karachi on 25-02-2021 to check the GMP compliance level of the firm, wherein following sample of drugs along with other drugs were taken for the purpose of test/analysis on prescribed Form-3:

Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Result of CDL
Cipracept 250mg Tablet	096357	TCA-103	01-2021	01-2023	M/s. Mission Pharmaceuticals (Pvt.) Ltd., Karachi.	Sub-Standard on the basis of Dissolution

FID sent sealed samples of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the test/analysis vide this office memorandum No. ARS-69-70/2021-FID-II (K) dated 26-02-2021

The Government Analyst, Central Drugs Laboratory, Karachi vide test report No.KQ.51/2021 dated 23rd April, 2021 declared the sample of the above-named drug as **"Sub-Standard"** quality under the Drugs Act, 1976, which is violation of Section 23(1) (a) (v) of Drugs Act, 1976 and rules framed there under.

FID issued an explanation letter of even numbers dated 28th April, 2021 and 24th May, 2021 to M/s. Mission Pharmaceuticals (Pvt.) Ltd., A-94, SITE Super Highway, Karachi for explaining their position in the matter for manufacturing, selling & distributing of above-mentioned substandard drug with the directions to recall the above batch from the market.

FID submitted that M/s. Mission Pharmaceuticals (Pvt.) Ltd., Karachi did not challenge the test report of CDL, Karachi. Firm mentioned that they checked dissolution test and found it well in limits as specified by USP.

FID submitted that M/s. Mission Pharmaceuticals (Pvt.) Ltd., Karachi has violated the Section 23(1) (a) (v) of Drugs Act, 1976, and recommended that:

i. Registration of their under-reference product may kindly be suspended/cancelled for a certain period.
ii. PSI may be carried out by panel of inspectors.
iii. Recalled stock should be destroyed as per SOP.

FID further submitted the name of MD and technical persons as provided by the firm:

i. Muhammad Aleem Mirza, Managing Director (CNIC No. 42201-7437635-3)
ii. Pahlwan Tanwari, Production Incharge (CNIC No. 42201-1989136-9)
iii. Jubair Ali Watio, Manager Quality Control (CNIC No. 45208-8699076-5)

The names provided by firm have been verified by Licensing Division. A show cause has been issued to following dated 07-01-2022.

M/s Mission Pharmaceuticals, S.I.T.E Super Highway, Karachi.	Mr. Muhammad Aleem Mirza, Managing Director M/s Mission Pharmaceuticals, Karachi.
Pahlwan Tanwari, Production Incharge, M/s Mission Pharmaceuticals,	Jubair Ali Watio, Manager Quality Control, M/s Mission Pharmaceuticals,

Karachi	Karachi.

M/s. Mission Pharmaceuticals, Karachi replied vide letter: MP/C-005/22 dated 03-03-2022. They mentioned that

> *"[…] they found that this batch was over wet mixing due to this reason although tablet passes in disintegrator test but in dissolution test is not released in given time period. Normal wet mixing time is 10-15 minutes but by operator mistake has run the mixer for 35 minutes. Granules become dense and after finding the blend all in process test hadness, disintegration test and friability was found in limit […]."*

Firm further requested to be heard in person to share investigation and CAPA.
Firm has been called for personal hearing.

Proceedings and Decision of 320th Meeting of Registration Board.

M/s. Mission Pharmaceuticals, Karachi submitted vide Ref No. MP/08/026/22 dated 29-08-2022 that they requested to extend the date as they received letter dated 29-08-2022, unable to reach on time due to flood in Sindh.

Decision: *"The Board after considering the facts of the case, request of the firm to grant another opportunity of personal hearing and after thorough deliberations acceded the request and provide them another opportunity of personal hearing."*

In view of decision of 320th meeting, they have been called for personal hearing.

Proceedings and Decision of 321st Meeting of Registration Board.

Mr. Pahlwan, Production Incharge and Jubair Ali, QC Manager appeared before the Board on behalf of M/s. Mission Pharmaceuticals, Karachi. He reiterated the same stance submitted earlier.

Decision:

"The Board after considering the facts of the case and after thorough deliberations decided:

i. **Immediate suspension of the registration of Cipracept 250mg Tablet (Registration No. 096357) for a period of six months from the date of communication of decision.**
ii. **Submission of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by the firm and its verification by following panel.**
    - **Mr.Abdur Rasool Shaikh, Additional Director, DRAP, Karachi.**
    - **Ms. Mahrukh Mughal, Assistant Director, CDL, Karachi.**
iii. **Recommendations of panel will be placed before Registration Board for decision.**

CASE NO. 07: MANUFACTURE & SALE OF SUB-STANDARD DIAGYL SUSPENSION, BATCH NO. 162 BY M/S SWISS PHARMACEUTICALS (PVT) LTD, KARACHI.

SURPRISED "INSPECTION OF M/S SWISS PHARMACEUTICALS PVT LTD, A -159, SITE SUPER HIGHWAY KARACHI STOCK ORDER NOT TO DISPOSE OF ON FORM-I

FID-VI, Karachi visited the premises of premises of M/s Swiss Pharmaceuticals (Pvt) Ltd., A/159 SITE, Super Highway, Karachi on 12-06-2018 and taken the following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3:

Name:	Diagyl Suspension 60ml
composition	Each 5ml contain 200mg Metronidazole
Registration No:	020229
Batch No:	162
Manufacturing Date:	06-2018
Expiry Date:	06-2021
Manufactured By:	M/s Swiss Pharmaceuticals (Pvt) Ltd., A/159 SITE, Karachi

02. The FID-VI, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.ARS-57-59/2018-FID-VI (K) dated 12-06-2018 as required under Section 19(3)(i) of the Drugs Act, 1976.

03. The Federal Government Analyst, CDL, Karachi declared the sample as of Sub-standard quality on the basis of Assay content (Percentage determined: 208.2%, Limit: 95.0%- 105.0%) vide test/analysis report No.R.KQ. 468/2018 dated 20th July, 2018.

04. In light of the above said test report; the FID served an explanation letter vide reference No. ARS-57-59/2018-FID-VI (K) dated 26-07-2018 to M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Super Highway, Karachi for explaining their position in the matter of manufacturing, selling and distributing of above mentioned substandard drug with direction to recall the above said batch from the market. The FID-VI inspected the premises as the results were very alarming and could be lethal if the drug under reference was distributed to masses. The stock were fresh and present at their nation wise distributor so the firm quarantined it till further investigation.

05. In response M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Super Highway, Karachi submitted their reply vide reference No. Nil dated 08-08-2018 wherein they submitted that the same out of specification assay results were due to **Mixing Error.** They also submitted that the whole batch quantity is lying under their quarantine and they want to destroy it under the supervision of FID. However they didn't apply for retesting from Appellate laboratory, NIH, Islamabad.

06. The FID-VI, Karachi provided the names of responsible persons which are as under:

S.No.	Name	Designation	CNIC
1	Muhammad Umair Feroz	Director	42000-0375898-3
2	Zahid Hussain Khan	Quality Control Incharge	42401-7324156-3
3	Munawar Sultana	Production Incharge	42101-2796675-4

07. The Division of Drug Licensing, DRAP Islamabad was requested to verify the names provided by the FID-VI, Karachi and provided the following names being responsible persons and technical persons.

M/s Swiss Pharmaceuticals (Pvt) Ltd., A/159 SITE, Karachi.	Hafiz Ferozuddin (Director/Chief Executive) M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Karachi.
Hafiz Muhammad Umair, (Director) M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Karachi.	Hafiz Muhammad Aamir, (Director) M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Karachi.
Hafiz Muhammad Saad, (Director) M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Karachi.	Ms. Munawar Sultana (Production Incharge) (42101-2796675-4) M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Karachi
Zahid Hussain (Quality Control Incharge) (42401-7324156-3) M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Karachi	

08. The FID has provided that M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachi has violated the section 23(1) (a) (v) of the Drugs Act, 1976 and rules framed there under and recommended to the Board that the recalled stocks is ordered to be incinerated and firm may be issued warning to uplift the GMP standards so that such failures may satisfactory be mitigated/addressed in future.

09. Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 3-59/2018-(QC) dated 19-11-2018 that why the following action(s) should not be initiated against you:

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

10. The show cause notice was served to the firm and accused persons but the firm did not submit their reply in response to show cause notice.

Proceeding and Decision of the 287th Meeting of Registration Board.

Mr. Hafiz Muhammad Umair (Director) and Mr. Zahid Hussain (Quality Control Incharge) of M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Karachi appeared on behalf of M/s Swiss Pharmaceuticals (Pvt.) Ltd., A/159 SITE, Karachi to plead instant case of Substandard drug Sub-Standard Diagyl Suspension, Batch No. 162 before the Board in its 287th meeting on 04th January, 2019. Representatives of firm informed that problem occurred due to improper mixing during manufacturing operation. The Board after hearing the accused deliberated the

matter in depth in the light of available record/ investigation report of FID decided as under:

I. Submission of product development data by the firm.

II. Product Specific Inspection including verification of product development data by the following panel:

- Director, Drug Testing Laboratory, Karachi.
- Area Federal Inspector of Drugs.

III. Suspension of the Registration of the said product for six (06) months or till the verification of product development data and satisfactory report by the panel whichever is later.

The decision of Registration Board had been communicated vide letter No. 03-92/2018-QC (287-RB) dated 28-02-2019.

FID-VI, DRAP, Karachi vide reference No.F.07-10/2020-FID-VI (K) dated 24th February, 2020 addressed to the Director QA&LT, DRAP, Islamabad regarding the subject of *"INSPECTION OF M/S HANDS PAKISTAN PLOT NO. 158, GADAP ROAD, MALIR KARACHI- STOCK ORDERED NOT OT DISPOSE OF ON FORM-1"* wherein ha has submitted that during the inspection of M/S Hands Pakistan Plot No. 158, Gadap Road, Malir Karachi on 24-02-2020 he recovered the stocks of Suspension Diagyl (R. No. 020229) for which the registration Board in its 287th meeting had suspended the registration of the said product for six months or till the verification of product development data and satisfactory report by the panel whichever is earlier. The available stocks of the suspended drug product were ordered "Not to dispose of on Form-1" under Section 18(1) of the Drugs Act, 1976 and violations of Board's decision.

S. No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Mfg. by
01	Susp. Diagyl 60ml	166 to 181	1 x 60ml x 134 x 100	10-2019	10-2022	M/s Swiss Pharmaceuticals (Pvt.) Ltd., Karachi.

Furthermore, samples of the said product along with other drugs were also drawn for test/analysis purpose on prescribed Form-3 and sent to the Federal Government Analyst, CDL, Karachi.

FID, DRAP, Karachi requested the permission for extension in the period of order made "Not to dispose of" on form-1 under the Drugs Act, 1976/DRAP Act, 2012. The permission was granted by Chairman, Registration Board and communicated to FID vide office letter F.No.3-59/2018-(QC) dated 08-05-2020 with directions to submit the complete case.

FID-VI, DRAP, Karachi vide reference No.F.07-10/2020-FID-VI (K) dated 04th March, 2020 addressed to the Director QA&LT, DRAP, Islamabad regarding the subject of "SURPRISED "INSPECTION OF M/S SWISS PHARMACEUTICALS PVT LTD, A -159,SITE SUPER HIGHWAY KARACHI STOCK ORDER NOT TO DISPOSE OF ON FORM I" wherein he has submitted that he was directed to inspect an unauthorized premises alleged to store expired drugs/ medicines and selling those after re labeling. Accordingly, the undersigned along with Dr. Waqar Ahmed Assistant Director DRAP Karachi proceeded for visit and reached at Plot No. C-36 SITE-II Super Highway Karachi. The alleged Plot was found owned by M/s Swiss Pharmaceutical (Pvt.) Ltd., and was very adjacent to their registered plot No. A/159 SITE Super Highway Karachi. The said plot is declared as their ware house on Drug Sale license and used for storage of expired goods and same was seen stored there. This plot is connected to their main plot No. A/159 through ill-defined stores where firm had stored some chemicals, packing materials and finished goods. Among the finished good panel found fresh stock of syrup Diagyl, B.No.170 and 171, the registration of which was suspended by the Board for six months are till the verification of product development data by the nominated panel vide DRAP Islamabad letter No.F.03-92/2018-QC (287-RB) dated 28th February 2019. But instead of complying the decision of the board concerned, the firm resumed the manufacturing of suspended drug. The suspected stocks were ordered not to dispose of initially for 28 days under section 18(1) of the Drug Act 1976.

S. No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Mfg. by
01	Susp. Diagyl 60ml	170	1 x 60ml x 100 x 110	12-2019	12-2022	M/s Swiss Pharmaceuticals (Pvt.) Ltd., Karachi.
02	Susp. Diagyl 60ml	171	1 x 60ml x 100 x 174	01-2020	01-2023	-do-

M/s Swiss Pharmaceuticals (Pvt.) Ltd., A-159 SITE Super Highway Karachi was directed to explain their position for manufacturing and selling of above suspended product vide this office letter of even number dated 24th February 2020. M/s Swiss Pharmaceutical (Pvt.) Ltd A-159 SITE Super Highway Karachi submitted their reply vide letter dated 03-03-2020 admitting their mistake and seeking further instruction

FID, DRAP, Karachi recommended that the registration of the alleged product may be cancelled after necessary legal procedure in this connection. The complete case is forwarded to your good office for further necessary action/instruction into the matter, please.

The permission was granted by Chairman, Registration Board and communicated to FID vide office letter F.No.3-59/2018-(QC) dated 08-05-2020 with directions to submit the complete case.
Reminder-I issued dated 15-06-2020.

FID-VI, DRAP, Karachi vide reference No.F.ARS-07-10/2020-FID-VI (K) dated 25-06-2020 regarding the subject of "Manufacture and sale of substandard drugs by M/s Swiss Pharmaceuticals (Pvt.) Ltd. Karachi" Wherein he has stated that he inspected M/s. Swiss Pharmaceutical (Pvt.) Ltd., A-159, SITE Super Highway, Karachi on 17-02-2020 and on 24-02-2020 FID, DRAP, Karachi inspected M/s. HANDS Pakistan, Plot No. 15, Gadap Road, Malir, Karachi.
During the inspections of both premises, following suspected samples were drawn along with other samples on prescribed Form-3 for test/analysis purpose:

S. No.	Name of Drug	Batch No.	Mfg Date	Exp. Date	Mfg by	Taken From	Result of CDL
01.	Susp. Diagyl 60ml	170	12-2019	12-2022	M/s. Swiss Pharmaceuticals (Pvt.) Ltd.,	M/s. Swiss Pharmaceuticals (Pvt.)	Substandard
02.	-do-	171	01-2020	01-2023	-do-	-do-	
03.	-do-	167	10-2019	10-2022	-do-	M/s. HANDS Pakistan, Malir, Karachi	

In the light of above test report of Government Analyst, Central Drugs Laboratory, Karachi an explanation letters of even numbers dated 09th March 2020 and 06th April 2020 were accordingly issued to M/s. Swiss Pharmaceuticals (Pvt.) Ltd., A-159 SITE Super Highway, Karachi
M/s. Swiss Pharmaceuticals (Pvt.) Ltd., A-159 SITE Super Highway, Karachi has submitted unsatisfactory reply and did not challenge the reports vide their letter dated 01th April 2020.
FID recommended that the firm has violated Section 23(1) (a) (v) and 23(l)(a)(x) of Drugs Act, 1976 for manufacturing and selling of Substandard and Suspended drug, which is punishable under Section 27 of Drug Act, 1976 and rules framed there under therefore, it is recommended that:-

1. The Drug Manufacturing License No. 000438 of M/s. Swiss Pharmaceuticals (Pvt.) Ltd., Karachi may be suspended/cancelled for certain period after due deliberation of Registration Board/Licensing Board.
2. The registration of the alleged product **(Suspension Diagyl)** may be cancelled for violation of decision of Registration Board
3. Through panel GMP inspection may be conducted.

Names of Responsible persons along with copies of CNICs as provided by the firm;

i. M/s. Swiss Pharmaceuticals (Pvt.) Ltd., A-159 SITE Super Highway, Karachi
ii. Muhammad Umair Feroze, Director (42000-0375898-3)
iii. Munnawar Sultana, Production Incharge (42101 -2796675-4)
iv. Safdar Khan Kayani, QC Incharge (42401-1779995-5)

M/s Swiss Pharmaceuticals (Pvt.) Ltd., vide reference No. nil dated 22-07-2020 received on 10-08-2020 addressed to the Chairman, Registration Board wherein M/s Swiss Pharmaceuticals has submitted that due to pandemic of COVID-19 and lockdown situation in Karachi, their staff were not able to attend office and due to this, they were inept to join office to respond your letters. Now we therefore, confirm through this letter to challenge the testing report of Central Drug testing Laboratory, Karachi in Appellate laboratory. Their request for retesting of the said product, which is not within the prescribed period under the law so their request was not acceded.
PSI report in compliance to 287th meeting:
FID inspected M/s. Swiss Pharma dated 01-02-2021 w.r.t. decision of 287th meeting of Registration Board communicated vide letter No. 03-92/2018-QC (287-RB) dated 28-02-2019.
The observation, findings and conclusion of report submitted by FID reproduced as:

"OBSERVATIONS OF CURRENT INSPECTION:
During the current inspection the panel inspected in details the respective production areas and QC Lab. The panel also reviewed in details the following documents.
1. The root cause analysis (RCA) carried out by the firm after failure of the product.
2. The Corrective and preventive action (CAPA) taken to avoid the occurrence and recurrence of such failures in future.

3. Respective utility which might be the possible source of failure.
4. SOP relating to QA and QC system and quality manual were also checked in detail.
FINDING OF THE PANEL:
After thorough inspection, people meet, documents reviewed the panel observed as follows:
1. In compliance to the directions contained in afore-mentioned DRAP Islamabad letter the firm started to investigate the root-cause of the failure against their approved SOP.
2. The firm had found during the detailed RCA that it was propeller/stirrer that was stopped in holding vessel during the filling operation that actually affected in the variation of in potency of the Diagyl Suspension 200mg/5mL, Batch Number 162.
3. After assessing the RCA of the failure the firm had taken CAPA for better product and process performance in the light of their approved SOP for Change Control Management. At present physical indicator with the tank is installed i.e. light system indication with the holding vessel propeller /mixer that indicates any type of malfunctioning propeller/mixer either mechanical or electrical failure during operation. (RCA attached
4. The firm also revised their Sampling procedure c f QA that will indicate any process failure during operation and incorporated in sampling SOP (SOP attached)
5. Re-trained their staff/operator (Training record checked and found satisfactory).
6. During suspension period three trial batches were also manufactured with revised formulation to further assess the product stability during its shelf-life. The respective data was reviewed in detail and found satisfactory results. (Copy annexed)
7. Overall the panel found that necessary RCA has been carried out by the firm and appropriate CAPA have been taken to avoid such failures again. Moreover stability trend of said product also found satisfactory during inspection. The Panel also found GMP conditions appropriate during the inspection.
8. The panel has checked the physical stock of Diagyl Suspension Batch No. 162 and found with the Firm, also the firm is agreed to incinerate the whole batch in the presence of DRAP Representative by third party and will submit the certificate of incineration to the DRAP Office.
Conclusion: Based on the above stated facts the panel concluded that the failure in assay was because of the utility failure and found other documents satisfactory, also firm did not utilize the stock of Diagyl Suspension B# 162 and is agreed to incinerate in the presence of DRAP representative, thus recommends the resumption of production of Diagyl Suspension."

The names provided by FID have been sent to the Division of Drugs Licensing to verify/provide the names for the period of October, 2019 for further processing of the case vide letter F.No.3-59/2018-QC dated 24-07-2020 with subsequent reminders dated 18-08-2020, 21-09-2020, 09-02-2021 and 06-12-2021. After verification of names from Licensing Division, a Show cause has been issued to firm dated 12-04-2022.

M/s. Swiss Pharmaceuticals (Pvt.) Ltd., Karachi replied vide ref no. nil dated 27-04-2022 wherein they requested to include their case in upcoming DRB meeting with PSI report for removal of suspension and approval to resume production as per the Drugs Act, 1976.

Evaluation of case:

Initially one sample was declared as Substandard which was discussed in 287th meeting of Registration Board held on 04-01-2019 where Board decided as under:

I. Submission of product development data by the firm.

II. Product Specific Inspection including verification of product development data by the following panel:

- Director, Drug Testing Laboratory, Karachi.
- Area Federal Inspector of Drugs.

III. Suspension of the Registration of the said product for six (06) months or till the verification of product development data and satisfactory report by the panel whichever is later.

Meanwhile, FID further submitted that he inspected:

1. M/S HANDS PAKISTAN PLOT NO. 158, GADAP ROAD, MALIR KARACHI dated 24-02-2020 and recovered the stocks of Suspension Diagyl (R. No. 020229) for which the registration Board in its 287th meeting had suspended the registration of the said product for six months or till the verification of product development data and satisfactory report by the panel whichever is earlier.

2. Plot No. C-36 SITE-II Super Highway Karachi. The alleged Plot was found owned by M/s Swiss Pharmaceutical (Pvt.) Ltd., and was very adjacent to their registered plot No. A/159 SITE Super Highway Karachi. The said plot is declared as their ware house on Drug Sale license and used for storage of expired goods and same was seen stored there. This plot is connected to their main plot No. A/159 through ill-defined stores where firm had stored some chemicals, packing materials and finished goods. Among the finished good panel found fresh stock of syrup Diagyl, B.No.170 and 171, the registration of which was suspended by the Board.

FID also sampled 03 Batches (167, 170, 171) of Diagyl suspension for test/analysis from above mentioned premises which were also declared Substandard by CDL, Karachi.

The PSI was conducted after 2 years of the decision of Board only for Batch no 162 and panel recommended for resumption despite of that firm has not comply with the decision of Board and manufactured multiple batches of the product after suspension. Further, 03 more batches have been declared Substandard on assay.

The firm representatives have been called for personal hearing.

Proceedings and Decision of 320th Meeting of Registration Board.

No person appeared before the Board on behalf of M/s. Swiss Pharmaceutical (Pvt.) Ltd., Karachi. Therefore, to meet the ends of justice, the Board decided to give one final opportunity of personal hearing to management of M/s. Swiss Pharmaceutical (Pvt.) Ltd., Karachi in its forthcoming meeting.

In view of decision of 320th meeting, they have been called for personal hearing.

Proceedings and Decision of 321st Meeting of Registration Board.

Mr. Huzaifa Umer, Director and Mr. Rashid Mureed, Lawyer appeared before the Board on behalf of M/s. Swiss Pharmaceutical (Pvt.) Ltd., Karachi. They reiterated the same stance submitted earlier. The Board after detailed discussion and thorough deliberations decided:

i. **Cancellation of the Registration of product namely Diagyl Suspension (Registration No. 020229).**
ii. **To prosecute the management of the firm, QCM, Production Manager through M/s Swiss Pharmaceutical (Pvt.) Ltd., Karachi, in the Drug Court, Karachi for manufacturing of substandard products during suspension period.**

Case No. 08: NON-SUBMISSION OF METHOD OF TESTING OF SASTALKA LIQUID BY M/S. SWAT PHARMACEUTICALS, SAIDU SHARIF SWAT

FID I Peshawar has submitted a letter vide No. F. 3-20/2021-DRAP-4842 dated 16-12-2022 wherein he said that he received test report (Form-6) from the Federal Government Analyst, Central Drugs Laboratory with the following remarks;

- Sample could not be tested due to non-receipt of method of testing.

Details are:

Name of Product	Reg No.	Batch No.	Mfg. Date	Exp. Date	Claimed to be manufactured by	Report No. and Date	Remarks of CDL
Sastalka Liquid	003048	L017	06-21	06-23	M/s. Swat Pharmaceuticals, Saidu Sharif Swat.	IP.59/2021 dated 27-08-2021	Sample could not be tested due to non-receipt of method of testing.

FID also seek further course of action in such matters to finalize the case.

The case has been reviewed and a show cause has been issued to M/s. Swat Pharmaceuticals, Saidu Sharif Swat after approval from Chairman, Registration Board to explain the position vide F.No.13-27/2022-QC dated 14-03-2022. No reply received.

Firm has been called for personal hearing.

Proceedings and Decision of 320th Meeting of Registration Board.

No person appeared before the Board on behalf of M/s. Swat Pharmaceuticals, Swat. Therefore, to meet the ends of justice, the Board decided to give one final opportunity of personal hearing to management of M/s. Swat Pharmaceuticals, Swat in its forthcoming meeting.

In view of decision of 320th meeting, they have been called for personal hearing.

Proceedings and Decision of 321st Meeting of Registration Board.

Mr. Fayaz Khan, QC Manager appeared before the Board on behalf of M/s. Swat Pharmaceuticals, Swat. They submitted method of test/analysis of the product before the board.

The Board directed the firm to submit method of analysis to Federal Government Analyst, Central Drugs Laboratory, Karachi and submit a copy along with dispatch receipt to Division of QA&LT, DRAP, Islamabad for record. Furthermore, the Board advised the Federal Government Analyst, Central Drugs Laboratory, Karachi to test the sample within 60 days.

Case No. 09: STOCKS OF DRUGS SEIZED UNDER SECTION 18 (1) OF THE DRUGS ACT, 1976 - M/S, PAK RISEN PHARMACEUTICALS, HATTAR.

FID-I Peshawar vide letter No. F. 3-20/2021-PakRisen-DRAP-3242 dated 12-08-2021 informed regarding the inspection of the firm M/s. Pak Risen Pharmaceuticals, Plot No. 3, Phase-I-II, Industrial Estate, Hattar on 06-08-2021 and has requested for the permission to continue the safe custody of seized stocks till the decision of case.

02. Details of stocks are given as under:

s. No.	Name of item	Reg. No.	B. No.	Mfg. date	Exp. date	Mfg. by	Qty.
1	Pakcezone 250mg inj	040388	DV-2I08	06/21	05/23	M/s Pak Risen Pharmaceuticals, Plot No. 3, Phase I II, Industrial Estate, Hattar.	1 Pack
2	Metrozine 100ml infusion alongwith Original Batch manufacturing record (36 pages)	040412	LV-2125	06/21	05/23	-do-	1 Pack
3	Metrozine 100ml Infusion alongwith Original Batch manufacturing record (36 pages)	040412	LV-21I0	03/21	02/23	-do-	1 Pack

02. The same was granted to FID-I Peshawar vide letter F. No. 13-43/2021-QC dated 21-10-2021. Furthermore, FID I Peshawar was instructed to provide complete investigation of case for further processing of the matter.

03. FID I Peshawar has submitted following reason to declare the sample of product Pakcezone 250 inj and Metrozine 100ml Infusion as misbranded product:

S. No.	Product name	Mfg date	Exp date	Mfg by	Reason to declare subject sample as Misbranded
1	Pakcezone 250mj Injection B. No. DV-2I08	06/21	05/23	M/s Pak Risen Pharmaceuticals, Plot No. 3, Phase I II, Industrial Estate, Hattar.	The product Pakcezone (Reg. No. 040388) is Ceftriaxone 250mg Injection while one side of packing (where MRP & Mfg. License No. is printed) bears Pakcezone Injection as 500mg.
2	Metrorize 100ml Infusion B. No. LV-2125	06/21	05/23	-do-	The batch record and all the documents indicate that product is manufactured in the month of July 2021 as mfg. date. However label bears manufacturing date as 06/2021. The record reveals that preprinted labels with old mfg. date i.e., 06/2021 were used and besides misbranded, its deliberate manipulation of documents and data integrity is deliberately breached.
3	Metrorize 100ml Infusion B. No. LV-2110	03/21	02/23	-do-	The batch record and all the documents indicate that product is manufactured in the month of April 2021 as mfg. date. However, label bears manufacturing date as 03/2021. The record reveals that preprinted labels with old mfg. date i.e., 03/2021 were used and besides misbranded, its deliberate manipulation of documents and data integrity is deliberately breached

03. FID I Peshawar vide letter No. 11-53/2005-PakRisen-DRAP 4690 dated 06-12-2021 submitted the complete case and recommended as under:

"Recommendations

Based on conclusion of the cases vide column 10 above, there is sufficient evidence to believe that the drug product namely;

1. *Packzone 250mg Injection (040388), Batch No. DV-2108 Mfg. date 06/21 and expiry date 05/23*
2. *Metrorize 100ml Infusion (040412), Batch No. LV-2125, Mfg. date 06/21 and expiry date 05/23 &*
3. *Metrorize 100ml Infusion (040412), Batch No. LV-2110, Mfg. date 03/21 and expiry date 02/23*

are misbranded under Section 3 (s)(iv) of the Drugs Act, 1976, prohibited under section 23(a)(iii) and is punishable under section 27(2)(b) of the Drugs Act, 1976 of the DRAP Act, 2012. The case of the firm regarding GMP noncompliance was discussed in 283rd meeting of Central Licensing Board (CLB). The board suspended the production of the firm and constituted three member's panel for the inspection of the firm for rectifications of reported GMP noncompliance (Annex-V). It is proposed that the direction may be issued to the firm for avoiding above referred violations and to submit CAPA in this regard, to be verified by already constituted panel by the CLB n its 283rd Meeting. In case, firm fails to comply and reported by the panel, matter may be treated under the above referred provisions of the Drugs Act, 1976/ DRAP Act, 2012."

04. in the light of investigations of the FID-I Peshawar, show-cause notice was issued accordingly to following:

i) M/s. Pak risen Pharmaceuticals, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar through its Proprietor

ii) Sabir Khan S/o Nannay Khan (Proprietor), M/s. Pak risen Pharmaceuticals, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar.

05. In response to the show cause notice issued to the management of firm, reply received is given as under:

> *"It is stated with great concern that we have received Show cause NoticefF.No.13-43/2021- QC) on dated 8th Feb 2022 regarding sales of Misbranded Drugs.*
>
> *Dear Sir, we have gone through this case (sample seized by the Honorable FID) in detail and conducted a proper and deep investigation and we found a conclusion that at the time of Honorable FID Sir's inspection the collection of seized sample were done by our store attendant (non technical) as responsible technical persons were accompanying the honorable FID in inspection at that situation of stampede as finished goods store & other storage places & areas were empty (as wittiness by the FID) those samples were collected from controlled shelf of Q.C retain sample room where we use to keep misprinted and faulty/rejected stuff (one sample each) just to study and training of our Q.A/Q.C Staff & Those samples were not to be meant for market dispatch/ For sale by any means at all.*
>
> *The actual position is that the Batch of Pakcezone 250mg Batch # DV-2108 sent to market for sale was truly proof readed and checked and then released. The false/misprinted was caught at the spot and was discrded in the presence of QC staff. The production department was intimated on time.*
>
> *In addition to that in Ser.No.2 & Ser.No.3 Metrorise Case (Batch # LV-2125, LV-2110) we have not increased rather decreased their expiry by one month because of the shortage of labels and extreme demand in market, in effort not to effect market demand (human health) and customer's need for their patients we did So, but honorable FID has recognized us that it's too against the law so, we assure you/him that we will not repeat this practice in future again.*
>
> *Moreover we have written about all the in-questioned (Claimed Misbranded) Products to our sole distributor Lyall Pur Pharma (Detail Enclosed) just on FID's Direction and advice for their recall But we are informed that they have zero stock of these Products.*
>
> *Still we apologizes you for this staff negligence work. We expect and request you for not being harsh and show a kind response please."*

06. The accused are called before the Board for personal hearing.

Proceedings and Decision of 320th meeting:

No person appeared before the Board on behalf of M/s. Pak Risen Pharmaceuticals, Hattar. Therefore, to meet the ends of justice, the Board decided to give one final opportunity of personal hearing to management of M/s. Pak Risen Pharmaceuticals Hattar in its forthcoming meeting.

In view of decision of 320th meeting, they have been called for personal hearing.

Proceedings and Decision of 321st Meeting of Registration Board.

Mr. Shoaib Khan, Admin and Mr. Asif Khan, Production Incharge appeared before the Board on behalf of M/s. Pak Risen Pharmaceuticals, Hattar. They reiterated the same stance submitted earlier and mentioned that their firm is under renovation. The Board after detailed discussion and thorough deliberations decided:

i. **Recommendations to the Central Licensing Board for suspension of sterile area (Dry powder Injection Cephalosporin and Large Volume parenteral) section.**
ii. **Suspension of the Registration of product namely Packzone 250mg Injection (Registration No. 040388) and Metrorize 100ml Infusion (Registration No. 040412) till resumption of production by CLB and submission of Root Cause Analysis and submission of CAPA in QA&LT Division for consideration of Registration Board.**

AGENDA ITEM NO. 02
APPELLATE TESTING CASES

Case No. 10: MANUFACTURE & SALE OF SUB-STANDARD PANTOLOON TABLET, REG. NO. 095091, BATCH NO. 5602 MANUFACTURED BY M/S. ROCK PHARMACEUTICAL LABORATORIES (PVT) LTD., RISALPUR.

The Federal Inspector of Drug Peshawar inspected the premises of M/s. Rock Pharmaceutical Laboratories (Pvt) Ltd on 22-09-2021 on form-3. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL Results
Pantoloon tablets	M/s. Rock Pharmaceutical Laboratories (Pvt) Ltd., Risalpur.	095091	5602	12-2020	12-2022	Sub-Standard on the basis of Dissolution.

02. Results of CDL on the basis of which sample under reference has been declared as Substandard are reproduced as under:-

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Identification	The identification test must identify Pantoprazole Sodium	Complies.	USP 43
2.	Dissolution (Acid Stage)	**Stage 1**: Each unit is not less than Q=%% i.e. 75+5+80%. **Stage 2**: Average of 12 units (S1+S2) is equal to or greater than Q (75%) and no unit is less than Q-15% (75-15=60%). **Stage 3**: Average of 24 units (S1+S2+S3) is equal to or greater than Q (75%). Not more than 2 units are less than Q-15% (75-15=60%) and no unit is less than Q-25% (75-25=50%).	**Stage 1** Tablet no. / (%) age. 1 / 1.01 2 / 1.73 3 / 1.72 4 / 1.72 5 / 2.96 6 / 1.32 **Does not comply.**	USP 43
3.	**Assay** Pantoprazole. (Label Claim 20mg/tablet)	90.0% to 110.0%	107.9% Complies.	USP 43

Remarks: 1) *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

FID has sent the explanation letter to explain their position dated 20-01-2022 regarding the violation of Drug Act 1976 and DRAP Act 2012.

The firm has submitted their reply dated 25-01-2022, wherein they requesting for retesting of product.

After receiving letter from firm, FID asked the firm to provide data/ information for Appellate testing as per decision of Drugs Registration Board's 313th meeting. The decision of the Board reproduced as:

i. The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.
ii. Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.
iii. Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case.

Firm submitted the OOS investigation dated 14-03-2022 to FID. CDL submitted the response dated 26-08-2022. The final decision of investigation is OOS valid. The remarks of Lab Manager:

"As the buffer stage results are not within the specification of any three stages of dissolution defined by USP. Hence no need of re-test."

Technical Evaluation of the case:

i. The product is available in USP 43
ii. The product was declared substandard on dissolution.
iii. CDL performed the test as per USP 43 Dissolution Test 1 while firm performed on USP 43 Dissolution Test 2.
iv. The requirement /condition to performed Test 2 is:
"If the product complies with this test, the labelling indicates that the product meets USP Dissolution Test 2."
v. There is no specific test mentioned on certificate of analysis nor on pack of the product. Therefore, as per USP 43, Dissolution Test 1 is performed by CDL.

Proceedings and Decision of 321st Meeting of Registration Board.

The OOS investigations and testing records submitted by M/s. Rock Pharmaceutical Laboratories (Pvt) Ltd., Risalpur and CDL, DRAP Karachi in compliance to decision of 313th meeting of Registration Board was discussed. Registration Board after detailed discussion and considering the facts of the case decided:

> "The sample of Pantoloon Tablets Batch No. 5602 will be sent to appellate lab for dissolution test, on the basis of which the sample was declared as Substandard by CDL, Karachi."

Case No. 11: MANUFACTURE & SALE OF SUB-STANDARD BIOFEN SUSPENSION, REG. NO. 046094, BATCH NO. SP-167, MANUFACTURED BY M/S. BIO-LABS PRIVATE LIMITED, ISLAMABAD.

The Federal Inspector of Drugs-I, DRAP Islamabad sampled Biofen Suspension from the premises of M/s. Bio-Labs Pvt. Ltd. Islamabad dated 03-08-2021. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Remarks of CDL
Biofen Suspension	M/s. Bio-Labs (Private) Limited, Islamabad.	046094	SP-167	06/21	05/23	Substandard on the basis of Bio-Burden.

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Pink coloured suspension in ambered plastic bottles.	Complies.	Mfg. Specs.
2.	Identification	The identification test must identify Ibuprofen.	Complies.	USP 43
3.	**Bio-Burden (TAMC)**	**Not exceed 100 cfu/ml. (General chapter<61>.**	**1.5 x 103 cfu/ml Does not comply.**	**USP 43**
3.	pH	3.6 to 4.6	4.3-Complies	USP 43
4.	**Assay** Ibuprofen. (Label Claim 100mg/5ml)	90.0% to 110.0%	95.7%- Complies.	USP 43

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

The sample of drugs sent to Government Analyst, CDL for test and analysis on form-4 dated 05-08-2021. Federal Govt. Analyst CDL Karachi vide report No.R.IP.70/2021 dated 06-10-2021 has declared the sample as "Sub-standard.

In the light of above test report of Federal Government Analyst, Central Drugs Laboratory, Karachi, FID directed firm to stop the sale and recall the said drug and explain their position.

M/s. Bio-Labs replied to FID dated 11-11-2021 where in they requested for retesting to Appellate Lab NIH Islamabad.

As per decision of 313th meeting of Registration Board regarding appellate testing, firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 23-12-2021.

M/s. Bio-Labs replied dated 06-01-2022 that no deviation has been observed during the testing of this batch. They mentioned in their OOS investigation report that:

> *"As per investigation of Stage-I and Stage-II and detailed review of BMR, the product is found ok with respect to bioburden test."*

Federal Government Analyst, CDL, Karachi submitted OOS investigation. The result of sample does not comply to the specification. Final decision is OOS is valid.

Firm has directed to submit method of testing and records vide office letter of even number dated 08-09-2022. Firm replied dated 10-09-2022 that they provided SOP for Microbiological limit test and test reports. As per documents submitted by firm, they performed the test by pour plate method and there results were in defined limits.

Technical Evaluation of the case:

7. The product was declared sub-standard on the basis of failure of Bio-Burden (TAMC) results.
8. Firm claimed that they performed Bio-Burden test as per USP and results are as per specification. CDL performed test as per USP 43. The limit of test as per USP is "Not exceed 100 cfu/ml". Result of CDL is 1.5 x 103 cfu/ml.
9. The method is based on visual inspection of the sample

Procedings and Decision of 321st Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. Bio-Labs (Private) Limited, Islamabad and CDL, DRAP Karachi was presented before Registration Board. The Board deliberated the case in detail as follows:

i. M/s. M/s. Bio-Labs (Private) Limited, Islamabad requested for Appellate testing. In compliance to the decision of 313th meeting of Registration Board firm and CDL were asked to submit Out of specification (OOS) investigation vide office letter dated 23-12-2021. The firm submitted the response dated 06-01-2022; provided OOS investigation and method of testing dated 08-09-2022. They mentioned that no deviation has been observed during the testing of this batch. While CDL submitted the response dated 15-03-2022 that the result of sample does not comply to the specification. Final decision is OOS is valid.

ii. Review of documents revealed that firm has performed the bioburden test by pour plate method. Moreover, FID mentioned remarks on Form-4 to perform Bioburden of sample.

Decision:

Keeping in view position narrated above, the Board did not accede the firm's request of appellate testing and decided to issue show cause notice to M/s. Bio-Labs (Private) Limited, Islamabad on manufacturing and sale of substandard "Biofen Suspension (Reg. No. 046094)" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration Board."

Case No. 12: MANUFACTURE & SALE OF SUB-STANDARD MAPARIX INFUSION, REG. NO. 050695, BATCH NO. L-21019 MANUFACTURED BY M/S. S.J.&G. FAZUL ELLAHIE (PVT.) LTD., KARACHI.

The Federal Inspector of Drug Karachi inspected the premises of M/s. National Institute of Child Health (NICH) Rafeeqi Shaheed Road Karachi. on 23-04-2021 wherein the sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3.

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	Result of CDL
01	Maparix Infusion (Vancomycin HCL)	050695	L21019	02/2021	11/2022	M/s. S.J&G Fazul Ellahi (Pvt) Ltd, Plot No. E-46, S.I.T.E. Karachi.	Standard

The sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi by FID for the purpose of test/analysis vide memorandum No. NO. DHB-06/2021 to 13/2021-FID-III (K) dated 26th, April, 2021.

Portion of Sealed sample was sent to Chairman, Registration Board, DRAP Islamabad by FID vide office letter of even number dated 26th, April, 2021.

A portion of sealed sample was sent to M/s. S.J&G Fazul Ellahi (Pvt) Ltd, Plot No. E-46, S.I.T.E. Karachi by FID vide office letter of even number dated 26th April 2021.

Pharmacist, National Institute of Child Health, (NICH) Rafeeqi Shaheed Road Karachi vide office letters of even number dated 26th April 2021 was asked by FID to provide bill warranty in connection with the purchase of above said drug.

Pharmacist, National Institute of Child Health, (NICH) Rafeeqi Shaheed Road Karachi vide their letter No.nil dated 07th June 2021 Provided the warranty of M/s. Parras Enterprises Flat No. 08, P.I.A. Shower Land, Block 01, Gulshan-e-Jauhar Karachi. in connection with the purchase of above said drug.

FID vide office letter of even number dated 07th June 2021, was asked M/s. Parras Enterprises Flat No. 08, P.I.A. Shower Land, Block 01, Gulshan-e-Jauhar Karachi. to verify the same and provide subsequent bill warranty in connection with purchase of above said drug.

M/s. S.J&G Fazul Ellahi (Pvt) Ltd, Plot No. E-46, S.I.T.E. Karachi. vide their letter SJG/REG/0839/2021 dated 02nd, June 2021, confirm the receipt of portion sealed samples of drugs under section 19(3) of drug Act 1976.

The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as Sub-Standard" quality vide their test report No.KQ.106/2021 dated 10th, June 2021**.**

Results of CDL on the basis of which sample under reference has been declared as Substandard quality are reproduced as under:-

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Off white powder in clear glass vial.	Complies.	Mfg. Specs.

2.	Identification	The identification test must identify Vancomycin HCl.	Complies.	USP 43
3.	pH	2.5 to 4.5	2.64-Complies.	USP 43
4.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
5.	Bacterial Endotoxin	NMT 0.33 USP Endotoxin unit/mg of Vancomycin	**Does not comply**	USP 43
6.	Assay Vancomycin (Label claim 500mg/vial)	90.0 to 115.0%	103.7% Complies.	USP 43

Remarks: The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.

FID issued an explanation letter of even number dated; 11th June 2021 to M/s. S.J&G Fazul Ella1hi (Pvt) Ltd, Plot No. E-46, S.I.T.E. Karachi for explaining their position in the matter of manufacturing/selling of above-mentioned Sub-Standard drug.

M/s. S.J&G Fazul Ellahi (Pvt) Ltd, Plot No. E-46, S.I.T.E. Karachi. vide their letter No. SJG/REG/0858/2021 dated 29th June 2021 requesting for retesting of Drug Maparix Infusion Batch No. L21019 from National Institute of Health (NIH) Islamabad.

FID stated that in the light of above, submission portion of sample lying with the Board may be got retested from Appellate Laboratory National Institute of Health (N.I.H) Islamabad.

In light of Supreme Court judgement of "C.P.1692-L/2020, C.P.1792-L/2020 and C.P.5-L/2021" and firm's request for appellate testing, the case is submitted for consideration of Board.

Proceedings and Decision of 312th Meeting of Registration Board.

The case has been deferred till the finalization of Appellate Testing Guidance Document/Protocol.

The agenda of "Handling requests of Appellate Testing- Guidance document for registration Board" was discussed in 313th meeting of Registration Board. The Board after thorough deliberations and considering the facts of the case decided as:

i. The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.
ii. Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.
iii. Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case.

OOS investigation was asked by firm and CDL vide office letter dated 23-12-2021.

The firm submitted the response dated 29-12-2021. They provided the SOPs and records but did not provide OOS investigation claiming they did not find any OOS.

CDL submitted the response dated 15-03-2021 wherein they mentioned : OOS is validated.

Technical Evaluation of the case:

- The product was declared sub-standard on the basis of results of Bacterial endotoxin.
- Endotoxin test performed by Gel Clot method both by firm and CDL as given in USP 43.
- The method is based on visual inspection of the sample after incubation for presence of gel or otherwise.

Proceedings and Decision of 317th Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. S.J&G Fazul Ellahi (Pvt) Ltd, Karachi and CDL, DRAP Karachi was presented before Registration Board. After thorough deliberations and considering the facts of the case, the Board decided and allowed to perform appellate test/analysis of sample (Maparix Infusion Batch no. L21019) to the extent of only that particular test (Endotoxin test) on basis of which the product was declared sub-standard by CDL, Karachi"

The sample of Maparix Infusion Batch no. L21019 has been sent to NIH as per the Board's decision.

Test report from NIH has been received dated 18-08-2022 with the conclusion:

"The sample is of standard quality on the basis of test performed."

Proceedings and Decision of 321st Meeting of Registration Board.

Report of NIH was presented before the Board. The Board directed QA&LT Division to forward the report to area FID for compliance (if any) and the firm M/s. S.J&G Fazul Ellahi (Pvt) Ltd, Karachi for their record.

Case No. 13: **SUBSTANDARD 25% DEXTROSE INFUSION B. NO. A042C21 MANUFACTURED BY M/S. OTSUKA PAKISTAN LTD., HUB, BALOCHISTAN.**

Federal Government Analyst CDL Karachi vide test report No. F. 5-3(K)/2021-CDL/S-1468 dated 03-12-2021 it was informed that the sample of product "25% Dextrose Infusion" Batch No. A042C21 (Mfg. date 31-03-2021, Exp date 30-03-2024) sent to CDL Karachi by FID-II Karachi has been declared as of substandard quality on the basis on non-compliance of pH specifications. Details of the test report are given as under:

S. No.	Test	Acceptance Criteria	Result	Reference
1.	Identification	The identification test must identify Glucose (Dextrose)	Complies	BP 2020
2.	pH	3.5 to 6.5	**2.73 – Does not comply**	BP 2020
3.	Bacterial Sterility	Must be sterile	Complies	BP 2020
4.	Endotoxin	The Endotoxin limit concentration is 0.25 IU/ml	Complies	BP 2020
2.	Assay Glucose (Dextrose), (Label claim 250mg/ml)	95.0% to 105.0%	96.80% Complies	BP 2020

02. FID-III Karachi vide letter No. F. ARS-19-25/2021-FID-III (K) dated 28-12-2021 forwarded the request of M/s. Otsuka Pakistan, Hub dated 23-12-2021 for appellate testing of their sample of product namely "25% Dextrsoe Infusion" batch No. A042C21 declared substandard by CDL Karachi on 03-12-2021.

03. It is submitted the Registration Board in its 313th meeting decided as under:

"Proceedings and Decision of 313th Meeting of Registration Board.

The Board after thorough deliberations and considering the facts of the case decided as:

i. The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.

ii. Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.

iii. Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case."

04. Therefore, in the light of decision of Registration Board, a letter vide No. F. 03-48/2021-QC dated 27-01-2021 was issued to M/s. Otsuka Pakistan, Hub for submission of OOS investigation and complete testing record of the concerned batch of product 25% Dextrose Infusion along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976 and to Federal Government Analyst CDL Karachi for submission of OOS investigation and complete testing record of report vide No. F. 5-3(K)/2021-CDL-S-1486 dated 03-12-2021.

Technical evaluation of OOS report by QC section:

05. M/s. Otsuka Pakistan Limited, Hub vide letter dated 15-02-2022 and CDL Karachi vide letter No.1-1/2013-SRK/CDL/-1069 dated 15-03-2022 provided OOS investigation. Comparison of the investigation is given as under:

S.	**Laboratory**	**Test Performed**	**Results**	**Standard Value**	**Remarks**
01	CDL Karachi	pH (BP 2020)	2.73	3.5 – 6.5	-
02	M/s Otsuka	pH (BP)	At the time of batch release: 5.38 **Retesting:** Sample 1:- 3.58 Sample 2:- 3.54 Sample 3:- 3.58	-do-	The results of retesting performed by the firm show a decline in pH value from 5.38 to 3.58 over a period on 10 months. Moreover, the value 3.58 is also very close to the lower acceptance criteria i.e. 3.5

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.
In view of decision of 320th meeting, they have been called for personal hearing.

Proceedings and Decision of 321st Meeting of Registration Board.

Out of Specification (OOS) investigations submitted by M/s. Otsuka Pakistan Limited, Hub and CDL, DRAP Karachi was presented before Registration Board. The Board deliberated the case in detail as follows:

i. M/s. Otsuka Pakistan Limited, Hub requested for Appellate testing. In compliance to the decision of 313th meeting of Registration Board firm and CDL were asked to submit Out of specification (OOS) investigation vide office letter dated 27-01-2022. The firm submitted the response dated 15-02-2022 while CDL submitted the response dated 15-03-2022.

ii. Review of documents revealed that the results of retesting performed by the firm show a decline in pH value from 5.38 to 3.58 over a period on 10 months. Moreover, the value 3.58 is also very close to the lower acceptance criteria i.e. 3.5.

Decision:

Keeping in view position narrated above, the Board did not accede the firm's request of appellate testing and decided to issue show cause notice to M/s. Otsuka Pakistan, Hub on manufacturing and sale of substandard product "25% Dextrose Infusion" Batch No. A042C21under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Otsuka Pakistan Limited, Hub and called them for personal hearing before Registration Board.

Case No. 14: SUBSTANDARD NYLOZ CAPSULE MANUFACTURED BY M/S. ZEPHYR PHARMATEC (PVT) LTD. KARACHI.

Federal Government Analyst CDL Karachi vide test report No. F. 5-3(K)/2021-CDL/S-870 dated 30-07-2021 wherein it was informed that the sample of product "Nyloz capsule (Esomeprazole 20mg)" Batch No. C01358 (Mfg. date 05-2021, Exp date 04-2023) sent to CDL Karachi by FID-II Karachi has been declared as of substandard quality. Details of the test report are given as under:

S. No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Hard gelatin capsule consist of yellow coloured body and green coloured cap containing white enteric coated pellets	Complies	Mfg. Specs
2.	Identification	Identification test must identify Esomeprazole Magnesium	Complies	USP 43
3.	Dissolution	Each unit is not less than 80%	Complies	USP 43
4.	Uniformity of dosage units by content uniformity	Acceptanc value of the 30 dosage units is less or equal L1% and no individual content of "any" dosage unit is less than [1-(0.01)(L2)]M not more than [1+(0.01(L2)]M	**L1=22.24 – Does not comply.**	USP 43
5.	**Assay.** Esomeprazole. (Label claim20mg/cap)	90.0% to 110.0%	Complies	USP 43

02. FID-II Karachi vide letter No. F. 000403/2018-FID-II (K) (Zephyr) dated 07-09-2021 forwarded the request of M/s. Zephyr Pharmatec (Pvt.) Ltd., Karachi dated 11-08-2021 for appellate testing of Board's portion of sample of their product namely "Nyloz capsule" batch No. C01358 declared substandard by CDL Karachi on 30-07-2021.

03. It is submitted the Registration Board in its 313th meeting decided as under:

*"**Proceedings and Decision of 313th Meeting of Registration Board.***

The Board after thorough deliberations and considering the facts of the case decided as:

i. *The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.*

ii. *Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.*

iii. *Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case."*

04. Therefore, in the light of decision of Registration Board, a letter vide No. F. 03-28/2021-QC dated 31-12-2022 was issued to M/s. Zephyr Pharmatech Karachi for submission of OOS investigation and complete testing record of the concerned batch of product Nyloz capsule along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976 and to Federal Government Analyst CDL Karachi for submission of OOS investigation and complete testing record of report vide No. F. 5-3(K)/2021-CDL-S-870 dated 30-07-2021.

Technical evaluation of OOS report by QC section:

05. M/s. Zephyr Pharmaceuticals Karachi vide letter ZP/0398/2022 dated 05-01-2022 provided the OOS investigation report. On technical evaluation of CDL Karachi OOS investigation report and OOS investigation report provided by manufacturer it was observed that both have performed the content uniformity test according to USP 43 specifications. However, the manufacturer claims the product to be of standard quality while CDL Karachi has reported the product to be substandard.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Out of Specification (OOS) investigations submitted by M/s. Zephyr Pharmaceuticals Karachi and CDL, DRAP Karachi was presented before Registration Board. The Board after discussion and considering the facts of the case and nature of test failed, decided as follows:

"Not to accede the firm's request of appellate testing and issue show cause notice to M/s. Zephyr Pharmaceuticals Karachi on manufacturing and sale of substandard product "Nyloz capsule (Esomeprazole 20mg)" Batch No. C01358 under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration Board."

Case No. 15: SUBSTANDARD DELMOL SUSPENSION MANUFACTURED BY M/S. DELTA PHARMA (PVT.) LTD., NOWSHERA.

Federal Government Analyst CDL Karachi vide test report No. F. 5-3(P)/2021-CDL/S-967 dated 17-08-2021 wherein it was informed that the sample of product "Delmol Suspension (Paracetamol 120mg/5ml)" Batch No. 151 (Mfg. date 05-2021, Exp date 05-2023) sent to CDL Karachi by FID-I Peshawar has been declared as of substandard quality. Details of the test report are given as under:

S. No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Pink colored suspension in amber color glass bottle	Complies	Mfg. specs
2.	Identification	The identification test must identify Acetaminophen (Paracetamol)	Complies	USP 43
3.	pH	4.0 to 6.9	Complies	USP 43
4.	**Assay** Acetaminophen (Paracetamol) (Label claim 120mg/5ml)	90.0% to 110.0%	**74.1% - Does not comply**	USP 43

02. FID-II Karachi vide letter No. F. 10-7/2021-Delta-DRAP-3665 dated 21-09-2021 forwarded the request of M/s. Delta Pharma (Pvt.) Ltd., Nowshera dated 27-08-2021 for appellate testing of Board's portion of sample of their product namely "Delmol suspension" batch No. 151 declared substandard by CDL Karachi on 17-08-2021.

03. It is submitted the Registration Board in its 313th meeting decided as under:

"Proceedings and Decision of 313th Meeting of Registration Board.

The Board after thorough deliberations and considering the facts of the case decided as:

i. *The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.*

ii. *Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.*

iii. *Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case."*

04. Therefore, in the light of decision of Registration Board, a letter vide No. F. 03-32/2021-QC dated 22-12-2022 was issued to M/s. Delta Pharma (Pvt.) Ltd., Nowshera for submission of OOS investigation and complete testing record of the concerned batch of product Delmol suspension along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976 and to Federal Government Analyst CDL Karachi for submission of OOS investigation and complete testing record of report vide No. F. 5-3(K)/2021-CDL-S-870 dated 30-07-2021.

Technical evaluation of OOS report by QC section:

05. M/s. Delta Pharma Nowshera vide letter No. 22/DP/2021 dated 22-12-2021 provided OOS investigation report wherein they provided a non-pharmacopeial UV Photometric test report, manufacturing process of product and sample preparation method for test/analysis. Moreover, the report provided was not a controlled document and no reference for testing method were provided.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Procedings and Decision of 321st Meeting of Registration Board.

Out of Specification (OOS) investigations submitted by M/s. Delta Pharma Nowshera and CDL, DRAP Karachi was presented before Registration Board. The Board deliberated the case in detail as follows:

i. M/s. Delta Pharma Nowshera requested for Appellate testing. In compliance to the decision of 313th meeting of Registration Board firm and CDL were asked to submit Out of specification (OOS) investigation vide office letter dated 30-07-2021. The firm submitted the response dated 22-12-2021 and CDL submitted their response.

ii. Review of documents revealed that firm was performed the assay test on non-pharmacopeial method while CDL performed as per USP 43.

Decision:

"Keeping in view position narrated above, the Board did not accede the firm's request of appellate testing and decided to issue show cause notice to M/s. Delta Pharma Nowshera on manufacturing and sale of substandard product "Delmol Suspension (Paracetamol 120mg/5ml)" Batch No. 151 under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration Board."

AGENDA ITEM NO. 03
ROUTINE CASES

Case No. 16: **MANUFACTURE & SALE OF SUBSTANDARD KLEVRA ORAL SOLUTION, REG. NO. 066831, BATCH NO. 0N152, MFG. DATE DEC. 2020, EXP. DATE DEC. 2022, MANUFACTURED BY M/S. PHARMEVO (PVT.) LTD. KARACHI.**

Test/analysis report No.KQ.57/2021 dated 20th March, 2021, from the Federal Government Analyst, CDL, Karachi received on 29-04-2021. Wherein, the Federal Government Analyst has declared sample of Klevra Oral Solution as of **"Sub-standard quality"**. Details are:

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	CDL Results
01	Klevra Oral Solution (Levetiracetam)	066831	0N152	Dec. 2020	Dec. 2022	M/s. PharmEvo (Pvt.) Ltd. Karachi	Sub-Standard on the basis of pH.

Results of CDL on the basis of which sample under reference has been declared as Substandard quality are reproduced as under:-

S.No.	Test	Specification	Result	Reference

1.	Description	Clear, and transparent solution having cherry flavor.	Complies.	Mfg. Specs.
2.	Identification	The identification test must identify Levetiracetam.	Complies	USP 43
3.	pH	4.8 to 6.3	**4.52** **Does not Comply.**	USP 43
4.	**Assay** Levetiracetam. (Lebel claim 500mg/5ml)	90.0% to 110.0%	98.4%- Complies.	USP 43

Note:- The product is included in USP 32 now; therefore, PharmEvo Specs. Should be removed as printed on the label.

Remarks: *The sample is **"Sub-Standard"** under the Drugs Act, 1976.*

FID has been asked to submit complete case vide office letter of even number dated 04-05-2021. The recall alert to manufacturer issued dated 04-05-2021.

M/s. PharmEvo (Private) Limited, Karachi submitted that the product is registered with Manufacturer Specification (MS) while CDL declared the product as of substandard quality on USP specification. They further said that as DRAP has under circular no. F.3-5/2020-I&VII (M-297) dated 27-01-2021; the board allowed 6-month time for implementation of the decision. They also requested to withdrawn the Drug recall from website of DRAP.

Registration division confirmed that product is registered on MS and renewed on 06-08-2020. Firm has not applied for change of specification of subject drug till date. Further, Firm has been manufacturing product under consideration with manufacturer's specification despite of inclusion of said formulation in USP which is against the decision of Registration Board and Central Licensing Board communicated vide letter no. F.3-2/2006-Reg-II-South (M-197) dated 05-06-2006 where in it was decided that firms may adopt their own specifications for the drugs which are not included in the official Pharmacopeias, till the inclusion of these formulations in the official pharmacopeias listed in Section-3 of Drug Act 1976. Furthermore, letter No.F.3-5/2020-I&VII(M-297) dated 27-01-2021 is issued in the context of labeling of specification due to which DTLs/QCLs declaring the products as "Misbranded" after deliberations/ discussion regarding the matter and does not apply if product is declared as Sub-Standard on being tested on official Pharmacopeia.

A letter has been issued to firm w.r.t. above decisions dated 02-08-2022.

M/s. PharmEvo Private Limited, Karachi submitted their reply in response to office letter dated 02-08-2021 wherein firm has mentioned that:

"The instructions of MOH/DRAP with regards to pharmacopoeial specifications stand suspended and have been held in abeyance by DRAP till January 26, 2022 vide notification circular No. F.3-5/2020-I&VII (M-297) dated 26-07-2021."

They further requested to withdraw the Medical product alert from DRAP website.

FID, DRAP, Karachi submitted the case details and recommended that:

> "As per Federal Government Analyst, CDL Karachi test report No KQ-57/2021 dated 20-04-2021, M/s. PharmEvo Private Limited, Karachi violated the Section 23(1)(a)(v) of the Drugs Act 1976 and rules framed there under."

The case has been submitted for consideration in light of above-mentioned decision of Registration Board.

Proceedings and Decision of 317th Meeting of Registration Board

Registration Board deferred the case and directed to present with the registration status of the product i.e. Klevra Oral Solution (Registration No. 066831) including approved specification of finished product for consideration of firm's request in next meeting.

Registration status was asked from Registration Division and following points have been revealed:

- The product was initially registered with the name of Equip Oral Solution Reg No. 066831vide letter No.F.3-6/2010 Reg-II (M-227) dated 08-10-2010 in name of M/s PharmEvo Pvt Limited Karachi.
- The brand name was changed to Klevera Oral Solution vide letter No.F.6-1/2011-Reg-II dated 10-02-2011.
- The finished product specifications of "Klevra Oral Solution" were changed from "Manufacturer's Specification" to "USP Specification" vide approval issued dated 19-11-2021

- The renewal for year 2015 was received on 19.08.2015 and for year 2020 was received on 06.08.2020. Both of aforesaid renewals are within time w.r.t date of registration.

Decision of 320th meeting of Registration Board

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board after discussion and by considering the facts of the case decided to issue show cause notice to M/s. PharmEvo Private Limited, Karachi on manufacturing and sale of substandard product "Klevra Oral Solution" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration Board.

Case No. 17: MANUFACTURE & SALE OF SUB-STANDARD MELOVETZ INJECTION, REG. NO. 102021, BATCH NO. 2199017 MANUFACTURED BY M/S. VETZ PHAARMACEUTICALS (PVT.) LTD., KOTRI,

FID-IV, DRAP, Karachi inspected the premises of M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Q-1, S.I.T.E., Kotri, Sindh on 31-05-2021; wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3:

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	CDL Results
01	Melovetz 10 Injection	102021	2199017	05-2021	04-2023	M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Q-1, S.I.T.E., Kotri, Sindh	Sub-Standard on the basis of pH.

The sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis vide memorandum No.SHM-NTF-35-37/2021-FID (K-IV) dated 03-06-2021

Portion of Sealed sample was sent to Chairman, Registration Board, DRAP Islamabad vide this office letter of even number dated 04-06-2021.

The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Sub-Standard" quality under the Drugs Act 1976 vide their test report No.KQ.161/2021 dated 27-07-2021**.**

Results of CDL on the basis of which sample under reference has been declared as Sub-Standard quality are reproduced as under:-

S.No.	Test	Specification	Result	Reference
1	**Description**	Yellow colored oily solution in ambered glass vial.	Complies	BP Vet. 2020
2	**Identification**	The identification test must identify Meloxicam.	Complies	BP Vet. 2020
3	**pH**	7.5 to 9.1	**13.45%** **``Does not Comply.**	BP Vet. 2020
4	**Assay** Meloxicam (Lebel claim 10mg/ml)	95.0% to 105.0%	99.8%-Complies	BP Vet. 2020

Remarks: The sample is **"Sub-Standard"** quality under the Drugs Act, 1976.

FID sent an explanation letter of even number dated 03rd August 2021 to M/s. Vetz Pharmaceuticals (Pvt) Ltd., Q-1, S.I.T.E, Kotri, Sindh for explain their position in the matter of manufacturing/selling of above-mentioned Sub-Standard drug. M/s Vetz Pharmaceuticals (Pvt) Ltd:, Q-1, S.I.T.E, Kotri, Sindh vide their letter No.Ref-DV- 002dated 16th August 2021 explain their position.

FID submitted that in the light of Federal Government Analyst, CDL, Karachi test report No.KQ.161/2021 dated 27th July 2021 M/s Vetz Pharmaceuticals (Pvt) Ltd:, Q-1, S.I.T.E, Kotri, Sindh involved in manufacturing & selling of Substandard drug Melovetz 10 Injection batch No.2199017 and violated the section 23(1)(a)(v) of the Drugs Act 1976 and rules framed thereunder.

FID recommended action under section 42 of the Drugs Act 1976; reproduced as: -

> "Where any person has been found to have contravened any of the provisions of this Act, or the rules in respect of any registered drug, the registration Board may, after

giving such person an opportunity of being heard, cancel the registration of such drug or suspend such registration for a specified period"

The firm submitted recall log which was sent to area FID for verification and reconcillation of stock. FID submitted the response dated 02-12-2021 where in he verified the stock i.e. 16 cartons each containing 120 injections corresponded to 1920 total quantity as mentioned in reconciliation form by firm.

FID submitted the names of responsible persons dated 20-01-2022 along with the reply of firm dated 10-08-2021 where in firm has mentioned that their product has in-house specifications while CDL test on pharmacopeial specification. The firm submitted to check their product by the method provided by manufacturer.

In view of firm's request of appellate testing and notification issued by Registration Division on subject "Compliance with Pharmacopial Specification" dated 07-02-2022, the case is submitted for consideration of Board.

Proceedings and Decision of 317th Meeting of Registration Board

Registration Board deferred the case and directed to present with the registration status of the product i.e. Melovetz 10 Injection (Registration No. 102021) including approved specification of finished product for consideration of firm's request in next meeting.

Registration status was asked from Registration Division and following points have been revealed:

- The product was registered with the name of Melovetz 10 Injection, Registration No. 102021vide letter No.F.7-1/2020-I&V-I (M-293) (Vet) dated 30-04-2020 in name of M/s Vetz Pharmaceuticals (Private) Limited, Kotri, Sindh.
- The finished product specifications of "Melovetz 10 Injection" are Innovator's Specification.
- Further registration letter condition xv shows that: "The innovator's specifications, however, are valid only till inclusion of the product in the official pharmacopoeia of reference countries as specified by the Registration Board"
- Since the product is available in official pharmacopoeia i.e. BP 2020, the tests performed as per BP 2020 by CDL Karachi.

Decision of 320th meeting of Registration Board

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board after discussion and by considering the facts of the case decided to issue show cause notice to M/s. Vetz Pharmaceuticals (Pvt) Ltd., Kotri on manufacturing and sale of substandard product "Melovetz 10 Injection" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration Board.

Case No. 18: **NON-SUBMISSION OF METHOD OF TESTING OF IPOMALT-F TABLETS BY M/S. ROCK PHARMACEUTICAL PVT LTD RISALPUR**

FID I Peshawar has submitted a letter vide No. F. 3-20/2021-DRAP-4842 dated 16-12-2022 wherein he said that he received test report (Form-6) from the Federal Government Analyst, Central Drugs Laboratory with the following remarks;

- Sample could not be tested due to non-receipt of method of testing.

Details are:

S.No.	Name of Product	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Claimed to be manufactured by	Report No. and Date	Remarks of CDL
01	Ipomalt-F Tablets	077301	7069	07-2021	07-2023	M/s. Rock Pharmaceutical Pvt Ltd Risalpur	IP.85/2021 dated 07-10-2021	Sample could not be tested due to non-receipt of method of testing.

FID also seek further course of action in such matters to finalize the case.

The case has been reviewed and a show cause has been issued to M/s. Rock Pharmaceutical Pvt Ltd Risalpur after approval from Chairman, Registration Board to explain the position vide F.No.13-27/2022-QC dated 14-03-2022.

Firm submitted reply dated 21-03-2022 wherein they said that no letter received from FID-I Peshawar. They further mentioned that upon receipt of QA&LT Division letter, they submitted complete method of testing along with COA of working standard.

Decision of 320th meeting of Registration Board

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board after discussion and considering the facts of the case decided:

> **"QA&LT Division will send the case along with receipts submitted by firm to Federal Government Analyst, Central Drugs Laboratory, Karachi with advise to test Ipomalt-F Tablets Batch no. 7069 within 60 days.**

Case No. 19: **NON-SUBMISSION OF METHOD OF TESTING OF WELOMEP INFUSION BY M/S. WELWRD PHARMACEUTICALS, HATTAR.**

FID I Peshawar has submitted a letter vide No. F. 3-20/2021-DRAP-4842 dated 16-12-2022 wherein he said that he received test report (Form-6) from the Federal Government Analyst, Central Drugs Laboratory with the following remarks;

- Sample could not be tested due to non-receipt of method of testing.

Details are:

Name of Product	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Claimed to be manufactured by	Report No. and Date	Remarks of CDL
Welomep Infusion	041593	V828	08-21	08-23	M/s. Welwrd Pharmaceuticals, Hattar.	IP.89/2021 dated 07-12-2021	Sample could not be tested due to non-receipt of method of testing.

FID also seek further course of action in such matters to finalize the case.

The case has been reviewed and a show cause has been issued to M/s. Welwrd Pharmaceuticals, Hattar after approval from Chairman, Registration Board to explain the position vide F.No.13-27/2022-QC dated 14-03-2022.

Firm submitted reply dated 16-03-2022 wherein they mentioned that they had send reply on proper time to Drug Testing Laboratory, Karachi dated 29-11-2021.

Decision of 320th meeting of Registration Board

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board after discussion and considering the facts of the case decided:

> **"QA&LT Division will send the case along with receipts submitted by firm to Federal Government Analyst, Central Drugs Laboratory Karachi with advise to test the sample of Welomep Infusion Batch no. V828 manufactured by M/s Welwrd Pharmaceuticals, Hattar within 60 days.**

Case No. 20: NON-SUBMISSION OF METHOD OF TESTING OF REMEP INJECTION BY M/S. AULTON PHARMACEUTICALS, HATTAR.

FID I Peshawar has submitted a letter vide No. F. 3-20/2021-DRAP-4842 dated 16-12-2022 wherein he said that he received test report (Form-6) from the Federal Government Analyst, Central Drugs Laboratory with the following remarks;

- Sample could not be tested due to non-receipt of method of testing.

Details are:

Name of Product	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Claimed to be manufactured by	Report No. and Date	Remarks of CDL
Remep Injection	080570	A6221	08-21	07-23	M/s. Aulton Pharmaceuticals, Hattar.	IP.88/2021 dated 07-12-2021	Sample could not be tested due to non-receipt of method of testing.

FID also seek further course of action in such matters to finalize the case.

The case has been reviewed and a show cause has been issued to M/s. Aulton Pharmaceuticals, Hattar after approval from Chairman, Registration Board to explain the position vide F.No.13-27/2022-QC dated 14-03-2022.

Firm submitted reply dated 15-03-2022 wherein they mentioned that after receiving reminder letter from FID regarding submission of specification and testing method of subject mentioned product dated 25-02-2022, they responded and submit the required documents dated 28-02-2022.

Decision of 320th meeting of Registration Board

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board after discussion and considering the facts of the case decided:

QA&LT Division will send the case along with receipts submitted by firm to Federal Government Analyst, Karachi with advise to test the sample of Remep Injection Batch No. A6221 manufactured by M/s Aulton Pharmaceuticals, Hattar within 60 days.

Case No. 21: MANUFACTURE & SALE OF SUB-STANDARD TEMPRIN TABLETS, BATCH NO. 055, MANUFACTURED BY M/S KOHS PHARMACEUTICAL (PVT.) LTD., HYDERABAD.

01. FID-VI, DRAP, Karachi inspected the premises of M/s. Hashmani Medicines, Shop No.4, Plot SB-1, Block-1, Madiha Square, Hussain abad, FB Area, Karachi on 21-11-2019 in light of NTF, wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name:	Temprin Tablet (Paracetamol 500mg)
Registration No:	070620
Batch No:	055
Manufacturing Date:	10/18
Expiry Date:	09/20
Manufactured By:	M/s. KOHS Pharmaceuticals (Pvt.) Ltd., P/8, SITE Hyderabad

02. The sealed samples of above drugs were sent by the FID, DRAP, Karachi to Federal Government Analyst, Central Drugs Laboratory, Karachi for test/analysis vide office memorandum No. ARS- 249-252/2019-FID-VI (K) dated 22-11-2019.

03. The sealed portion of the sample was also sent to Chairman, Registration Board vide letter No.F.249-252/2019-FID-VI (K) dated 22-11-19 as required under the provision of clause (b) (3) Schedule-V (Procedure for Inspector) of DRAP, Act, 2012.

04. M/s Hashmani Medicines, Karachi has produced the invoice/bill warranty No. 183 dated 25-09-2018 of M/s KOHS Pharmaceuticals (Pvt.) Ltd., P/8, SITE Hyderabad as a proof of their purchase of above said drug.

05. The Federal Government Analyst, Central Drug Laboratory, Karachi vide test report No.NTF.KQ.567/2019 dated 11-12-2019 declared the sample of above-named drug as "substandard" quality under the drugs Act, 1976, which is violation of Section 23 (1)(a)(v) of the drugs Act, 1976 and rules framed there under. Results of the test reports of CDL, Karachi are given as under;

Description:	*White tablets, marked with "KOHS" on one side and line of bisection on the other.*
Identification:	*Paracetamol identified.*
Dissolution test:	***Does not comply.***
Uniformity of Dosage Unit by Weight Variation:	*Complies.*

Assay for Paracetamol:	*Determined amount/tablet:*	*501.3477mg*
	Stated amount/tablet:	*500mg*
	Percentage:	*100.3%*
	Limits:	*95.0% to 105.0%*
	Complies.	

Remarks:- *The sample is of substandard quality under the Drugs Act. 1976.*

06. In light of the above test report of Government Analyst, Central Drugs Laboratory, Karachi explanation letters dated 16-12-2019, 30-12-2019 and 14-02-2020 were accordingly issued by the FID to M/s. KOHS Pharmaceuticals (Pvt.) Ltd., P/8, SITE Hyderabad for explaining their position in the matter of manufacturing, selling & distributing of above-mentioned substandard drug with the directions to recall the above substandard drugs from the market but the firm had not replied.

07. FID-VI, DRAP, Karachi further submitted that keeping in view of above stated facts, M/s. KOHS Pharmaceuticals, P/8, SITE, Hyderabad has violated Section 23(l)(a)(v) of Drug Act, 1976 and rules framed there under therefore, it is recommended that:-

i. The registration of said product may be suspended/cancelled in larger public interest after due deliberation of board concerned.
ii. It is also recommended that a detailed panel GMP inspection of the firm may be carried to find out the RCA of the problem and for final recommendations, please.
iii. The names of their Director and Technical persons may kindly be obtained from Licensing Division.

08. FID-VI, DRAP, Karachi vide reference No.F.ARS-249-252/2019-FID-VI (K)-NTF dated 26-02-2020 addressed to the Assistant Director (QC-II) wherein he has enclosed the reply of M/s KOHS Pharmaceuticals (Pvt.) Ltd., P/8, SITE, Hyderabad and also provided the names of following technical persons;

- Dayo Mal Daya Ram, MD (CNIC: 41306-33000997-5)
- Mirza Salim Ullah, Production Incharge, (CNIC: 41303-1504590-5)
- Miss Rakhshanda Parvenn, QC Incharge, (CNIC: 45304-9856804-2)

09. Drugs Licensing Division was requested to verify the names provided by the FID, DRAP, Karachi and they provided the following names;

i.	Mr. Pardeep Kumar	Director
ii.	Saman Mal	Director
iii.	Mr. Mirza Saleemullah	Production Incharge
iv.	Ms. Rakhshanda Parveen	Quality control Incharge

10. Show-cause notice was issued to the firm and above accused vide letter No.F.03-62/2029-QC dated 15-09-2020 for the following actions;

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

11. M/s. KOHS Pharmaceuticals (Pvt.) Ltd., Hyderabad submitted their reply vide reference No.032KOHS/2020-2021 dated 02-10-2020 and is given as under;

> *"Regarding to our product Temprin 500mg tab (Batch No. 055) was not complies in dissolution may be because of shop premises (Temperature & Humidity) not suitable for product or any atmosphere reason.*
> *Here we perform dissolution of temprin 500mg tab of other batches (070, 072) in our lab, the result of batch are within the limit, attach lab report copies.*
> *Kindly consider our lab report and give us one warning or to appear technical person in front of the Board."*

12. The accused were called before the Registration Board for opportunity of personal hearing.

13. The case was presented in the 297th meeting of the Registration Board wherein it was decided as under:

> *"i. To issues show cause notice for cancelation/suspension of the registration of product Temprin (Reg. No. 070620) to the accused.*
> *ii. The Board authorized Additional Director QA&LT to nominate a panel for inspectors to conduct the risk-based inspection of the firm including Dr. Rafiq Alam (Member Registration Board) and to take sample for test/analysis. Until satisfactory GMP inspection report and standard test report by CDL is obtained, the registration of product Temprin tablet will remain suspended."*

14. The accused were issued show-cause notice and notice of suspension of production of product vide No. F. 03-56/2021-QC (Pt-I) (297-RB) dated 05-04-2021. The accused has replied vide ref. No. 065/21/KOHS dated 15-04-2021 which is given as under:

"We have received your above latter, regarding our product Temprin tablet Batch No: 055 MFG date OCT / 18 EXP: SEP / 20

In this respect it is submitted that according to test analysis report issued from CENTRAL DRUGS LABORATORY / GOVT ANALYSIS report No NTF, KQ 567/ 2019,the potency of the said product is declared (100.3%). But it is not complying the dissolution test .I will attached photocopy of govt ,analysis test report for your kind of consideration. due to this reason it was declared as the sub -standard .kindly consider this matter sympathically

We had not appeared before the board official due to some environmental problems occurring in the country since last months.

Lastly it is requested that give us a chance for appearing before the Board Officials .regarding this matter."

15. The representatives of firm are called before the Board for personal hearing.

16. Proceedings and decision of 307th meeting of Registration Board:

Mr. Rashid Mureed (Attorney) appeared before the Board on behalf of M/s. KOHS Pharmaceuticals, Hyderabad to plead the instant case. The Board after considering the facts of the case, stance of the firm and thorough deliberations decided as follows:

i. The suspension of Registration of the Temprin tablet Registration No. 070620 remain intact till the PSI is conducted.
ii. The data of Quality Control cases during last 2 years along with their fates will be presented before the Board.

17. In compliance to the decision of 307th meeting of Registration Board, data of Quality Control cases along with the fates of the cases of M/s. KOHS Pharmaceuticals, Hyderabad were obtained from CDL Karachi and Provincial Health Departments. Details are given as under:

S. No.	TRA No. & date	Brand Name	Batch No.	Test result	CDL/DTL	Status of case
01	01-77002870 dated 2-27-2021	Tempramine suspension	TM047	Substandard based on Assay (65.20%) and physical description (sedimented cake)	Bahawalpur	Firm has submitted evidence in contravention of DTL report. Request of the firm will be placed in upcoming meeting of PQCB scheduled to be held on 20th January.
02	01-77002960 dated 03-03-2021	Tempramine suspension	TM047	Substandard based on Assay (65.20%) and physical description (sedimented cake)	Bahawalpur	Complete investigation report from Drug inspector has been received in PQCB Punjab.
03.	01-75000571 dated 03-03-2021	Tempramine suspension	076	Misbranded (Section 3(iv) of the Drugs Act 1976)	Rawalpindi	Complete investigation report Drug inspector is awaited by PQCB.

18. Moreover, FID-IV Karachi has submitted report in compliance to the decision of Board. Details of proceedings of inspection area given under:

"Focus of inspection:

Risk based product specific inspection in compliance to DRAP, Islamabad letter No. F. 4-18/2006-QA dated 30th June, 2021.

Proceedings of current inspection:

The panel during the inspection reviewed the available documents of the product Batch in question and interviewed the technical staff. Related documents and traceability was established with the log books and the practices being followed in manufacturing and testing of the product.

Production Premises:

Firm has provided properly maintained visitors change room, male and females staff change room along with a buffer before entrance into the production premises. Material receiving bays, quarantine area, storage, dispensing areas were visited and their log documents were reviewed at the work stations.

Quality Control Laboratory

The laboratory is equipped with necessary equipments for carrying out test/ analysis of the focused Dosage form i.e. Tablet. Hardness tester, Disintegration apparatus, dissolution apparatus, analytical weighing Balance, pH meter, UV-Spectrophotometer, HPLC and other facilitating equipments required for test/ analysis of the product were seen available and utilized for investigation at time of inspection.

Quality Assurance/ Documentation System:

Firm has basic documentation system in place. Batch Manufacturing record of the product and batch in question was reviewed and it reveals that most parameters are not defined in details although followed/ are in practice.

Technical Areas:

The HVAC units of this section are placed on the rooftop. Since, production in this section is suspended therefore, was not in operation at the time of inspection, However, supply and exit ducts were seen properly installed.

Observations/ Findings:

Process validation and stability, studies as per requirements were not satisfactory.

Recommendation and Conclusion:

Based on the areas visited, processes reviewed and technical people interviewed, the panel is of the view to recommend resumption of suspension of product "Temprin 500mg" subjected to submission and verification of process re-validation studies and stability data of 3 Batches upon resumption of production by the area FID."

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board deferred the case for further deliberation in next meeting.

Case No. 22: CASE REFERED BY PQCB, PUNJAB REGARDING REGULATORY METHOD OF ANALYSIS OF HEMOROSE-F TABLETS SUBMITTED BY M/S NEOMEDIX PHARMA.

01. The Secretary, Provincial Quality Control Board, Punjab vide reference No. PQCB/F-Isu-Bwp-05/06/19 dated 20-02-2019 has informed that Director DTL Faisalabad vide letter no. 8054/DTL/FSD dated 26-01-2019 stated that the lab has received sample of Tab. Hemorose-F (iron polymaltose complex + Folic acid) manufactured by M/S Neomedix bearing batch No. 484 from Drug Inspector Aziz Bhatti Shaheed Teaching Hospital Gujrat on 27-12-2018.

02. That requests for the provision of method was sent to manufacturer vide letter no. 6007/DTL/FSD dated 29-12-2018 and 23-01-2019 respectively. The method of analysis was found to be not workable for folic acid as the mentioned concentration (0.00007 mg/ml) for both sample and standard was below the limit of identification and quantification on UV at 280nm.

PROCEEDINGS AND DECISION:

03. Subject issue was considered by the Committee of the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 6th meeting held on 20-02-2019. Secretary PQCB apprised the Committee about background of the subject matter which was discussed at length and directed Drugs Testing Laboratory, Faisalabad to file the above-mentioned case. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specification and method of analysis to the Government analyst/Drug Testing Laboratories. The need for product specifications /method of analysis becomes more critical when the drug is not available in official pharmacopoeias and/or the manufacturer has its own customized specifications/method for analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample on such method provided by the firm on which sample as well as standard is not responding. The Board expressed its serious concerns over casual behavior on the part of the firms in this regard.

04. The Committee after due discussion and deliberation unanimously decided to recommend DRAP for the cancellation of registration of the above-mentioned product as the manufacturer ignored the dissolution criteria of the official monograph and also provided a method to the Govt. Analyst which is full of mistakes.

Proceeding and Decision of 291st meeting of Registration Board.

05. The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019 and the Board after detailed discussion decided as under:

"To issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore. You failed to fulfill the condition of registration as prescribed under the rules because the method of test/analysis method provided by you was non responsive for test analysis of Folic acid and is defective. (The method of analysis was found to be not workable for folic acid as the mentioned concentration (0.00007 mg/ml) for both sample and standard was below the limit of identification and quantification on UV at 280nm.). You are required to explain your position that why the registration of your product i.e. Tab. Hemorose-F (iron polymaltose complex + Folic acid) should not be suspended/cancelled."

06. Show cause notice was served to the firm as per decision of the Registration Board vide No.F.03-41/2019-QC (291st RB) dated 25-10-2019.

07. M/s Neomedix Pharma, Islamabad submitted their reply vide reference No. nil dated 06-11-2019 addressed to the Secretary, Registration Board regarding the subject of RE: Letter No.03-41/2019-QC Dated 25th October, 2019 wherein they have stated that "we would like to thank you for offering us the opportunity to be heard in person. Kindly give us a suitable date and time so we pay appear to your kind office and explain our case in detail."

Proceedings of 293rd meeting of the Registration Board.

08. Malik Shahid GM, (37405-4576435-1) and Ghulam of M/s Neomedix Pharma appeared on behalf of M/s Neomedix Pharma for instant case and stated that Quality Control Manager of the firm at that time submitted the method of analysis to the Provincial Quality Control Board which was not was not working/responding. Later on they submitted a new & validated method to the Provincial Quality Control Board but they told that it's too late now.

Decision of 293rd meeting of Registration Board.

09. Registration Board in its 293rd meeting after detailed discussion decided as under:

i. Suspension of the Registration of the said product for six (06) months or till the verification of root cause analysis, Corrective and preventive action (CAPA) by the firm, product development data and verification of aforementioned points and Product Specific Inspection by following panel whichever is later.
   - Dr. Qurban Ali, Member Registration Board
   - Area Federal Inspector of Drugs.
   - Mr. Haseeb Tariq AD PEC

10. The decision of the Board was communicated to the panel vide letter No. 03-65/219-QC-(293rd RB) dated 21-04-2020 wherein the Federal Inspector of Drugs-II Islamabad submitted as under:

"Kindly refer to the subject cited above and letter No.03-65/2019-QC- (293rd RB) dated 21-04-2020. It is submitted that a panel comprising of following members namely Dr. Qurban Ali Member Registration Board area FID and Mr. Haseeb Tariq AD, PEC was constituted with a direction to area FID-II implement the decision of the in letter in spirit and delivery of letter to the firm.

02. The letter has been delivered to the firm and case was discussed with members of the panel who opined that if the firm provides the CAPA then inspection may not be necessary. The firm on 07-08-2020 provided a CAPA report along with all Batch history of batch No. 484 in 2018 and 2020 and same has been forwarded to members with the points raised for PSI. The firm complied with the documentary evidence of CAPA and batch record. The members of the panel in consonance with the member registration Board (Dr. Qurban Ali). The panel in the light of evaluation of submitted documents (CAPA) by the firm is of opinion that the inspection may not be necessary for the said product. The same copy of the CAPA has already been submitted AD QC-II. The firm provided the report (BMR) and the test analysis reports dated May 2020 July 2020 same has been provided and sent to the members for perusal and directions. No directions/comments received from the members so letter is being sent to the Secretary Registration Board for record please."

11. In the above-mentioned reply, FID-II Islamabad has stated that the firm submitted CAPA to the panel members. The panel members were of opinion that in the light of submitted CAPA, the inspection may not be necessary.

12. Contrary to the statement of FID-II Islamabad, no such reply/comment/consonance has been received from the other panel members and also as per available record in the section no CAPA has been received from neither the firm nor FID-II Islamabad.

13. FID-II Islamabad vide letter No. F. 03-13/2005-FID-I(Isd) dated 14-06-2021 submitted the request of firm for resumption of production as under:

"In continuation of this office letter of even No. dated 20th August 2020 (Copy enclosed). The subject matter has been discussed with the members of panel, regarding the product namely Hemorose-F Tablet which had been suspended since more than six months as per decision of Registration Board taken before in its 293rd meeting held on 06-08th January 2020 (Copy enclosed). The firm had not manufactured the subject product since more than six months (copy enclosed).

02. In view of directions of the Registration Board the firm had complied with the decision of the Board and now requesting for resumption of production of Hemorose-F Tablet (Copy enclosed) which had been suspended. The panel members had also been kept on Board and agreed to the decision/ directions of Registration Board."

Proceedings and Decision of 312th meeting:

14. The Board after thorough deliberations and considering the reply of area Federal Inspector of Drugs discussed the matter with the other panel members i.e. Dr. Qurban Ali and Mr. Haseeb Tariq. Both members were unaware of such communication as stated by area Federal Inspector of Drugs. The Board showed serious concern over the reply of area Federal Inspector of Drugs and decided as under:

i. Suspension of the Registration of the said product till the verification of root cause analysis, Corrective and preventive action (CAPA) by the firm, product development data and verification of aforementioned points and Product Specific Inspection by following panel whichever is later.
    a. Dr. Qurban Ali, Member Registration Board
    b. Ms. Mehwish Tanveer, Assistant Director QA&LT
    c. Mr. Haseeb Tariq Assistant Director PEC

ii. Refer the case to Chief Executive Officer DRAP for taking disciplinary action against the area FID Islamabad for not complying Registration Board directions and mis-quoting other members of Registration Board.

15. In compliance to the decision of Registration Board, panel mentioned in para. 14 (i) visited the premises of M/s. Neomedix Pharmaceuticals Islamabad on 06-04-2022 for the purpose of verification of Root cause analysis, Corrective and preventatinve action and product development data for Hemorose-F tablet. Details of report as under:

"DETAILS OF INSPECTION

The firm was informed about the schedule of the inspection vide letter No. F. 15-1/2022-PRC dated 1st April 2022 by Assistant Director (PEC-III) after coordination with other panel members.

The panel visited the factory premises of M/s Neomedix located at Plot No. 05, N/5 National Industrial Zone, Islamabad on 06-04-2022. The following representatives / management of the firm were present at the premises:

1. *Mr. Faisal Muzamal (Partner)*
2. *Mr. Syed Talib Hussain Hashmi (Partner)*
3. *Ghulam Ghaus (QC Manager)*
4. *Muhammad Shoaib (Production Manager)*

The management of the firm informed the panel that they have recently purchased this unit and applied for change of management in Licensing Division DRAP in January 2022. The management informed that they have not yet got the complete possession of this unit and therefore no production activities are carried out. The firm also presented copy of letter for change of management of M/s Neomedix dated 4th July 2022 submitted to the Secretary Licensing Board (Annexure-I). The management further informed that since they have recently purchased the unit therefore they have not completed Root Cause Analysis, Corrective and Preventive Action (CAPA) and product development data for Hemorose-F tablets.

The management submitted a written request for provision of some time for performing Root Cause Analysis, Corrective and Preventive Action (CAPA) and product development data for Hemorose-F tablets (Annexure-II). The written request of the firm is as below:

Dear sir,

Referring to your letter No. F.15-1/2022-PEC dated 1st April 2022 and visit of inspection panel on 6th April, 2022, it is submitted that we have purchased this premises and submitted the letter of change of management in Licensing Division DRAP, in first week of January (Letter attached) and according to agreement, we will get complete possession of Neomedix in May 2022.

It is submitted that due to change of management and that till date we have not received full possession of premises, we have not completed Root Cause Analysis, CAPA and product development.

Kindly grant us 90 days after the full possession, so we could complete RCA, CAPA and product development in a better way.

Thanks and best regards,

For Neomedix,

Faisal Muzamal *Syed Talib Hussain*

(Partner) *(Partner)*

The management of the firm showed positive attitude for performing Root Cause Analysis, Corrective and Preventive Action (CAPA) and product development data for Hemorose-F tablets. The request of the firm is submitted for consideration by the Registration Board."

16. Proceedings and Decision of 317th Meeting of Registration Board.

Registration Board after thorough discussion and deliberations and considering the report of PSI and firm's request decided to advise panel for inspection of the firm in June 2022 for verification of CAPA and submit a report for consideration of the Board.

17. In compliance to the decision of the Board, the panel once again visited M/s Neomedix Pharma, Islamabad and submitted the report as under:

"DETAIL OF INSPECTION

The panel visited the factory premises of M/s Neomedix located at Plot No. 05, N/5 National Industrial Zone, Islamabad on 30-06-2022. The following representatives / management of the firm were present at the premises:

1. *Mr. Faisal Muzamal (Partner)*
2. *Mr. Syed Talib Hussain Hashmi (Partner)*
3. *Ghulam Ghaus (QC Manager)*
4. *Muhammad Shoaib (Production Manager)*
5. *Tauqeer Zehra (QA Manager)*

The management of the firm informed the panel that they have not yet conducted the Root Cause Analysis, Corrective and Preventive Action (CAPA) and performed product development and stability studies, because they have got the complete possession in May 2022 and afterwards they have started to upgrade the QC lab and have placed an order for the purchase of new HPLC system. The firm's management informed that they have received HPLC which needs commissioning and training which may take 15 days, after which they will perform product development studies.

Since the firm had not yet conducted the Root Cause Analysis, Corrective and Preventive Action (CAPA), product development and stability studies therefore the panel could not verify any performance of above stated studies."

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board after discussion, considering the facts of the case decided:

"To issue show cause notice to M/s. Neomedix Pharma, National Industrial Zone, Rawat under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

Case No. 23: NOT TO DISPOSE OF UNDER SECTION 18(1)(I) OF DRUGS ACT, 1976 – M/S. HAWK BIO PHARMACEUTICALS PVT LTD, PLOT NO.10, STREET NO. S-6, NATIONAL INDUSTRIAL ESTATE, RCCI RAWAT.

01. A letter was received from Federal Inspector of Drugs-III Islamabad, vide letter No. F.2-10/2011-FID-II dated 14th October, 2019, wherein FID requested Chairman, Drug Registration Board, for extension in order not to dispose of which was granted to FID-III Islamabad vide letter F. No. 13-195/2019-QC dated 30-12-2019 with instructions to complete the investigation. Details of the stock ordered not to dispose of are given as under:

S.#	Name of Drug	Batch No & Quantity	Manufacturer	Reason
01.	Invermectin	201808021 1.7 Kg	Unknown	The Firm's management is unable to provide the import authorization/ clearance

				documents of material issued by (I&E) DRAP.
02.	Bismuth Subnitrate	19030211 4.1kg	-Do-	-Do-
03.	Ferrous Sulphate	00118-060 22.250Kg	-Do-	-Do-
04.	Copper Sulphate	RLFX-873-18 19.90kg	-Do-	-Do-
05	Zinc Sulphate	JXBHB2019-014 17.7Kg	-Do-	-Do-
06	Magnesium Sulphate	Not Known 50Kg	-Do-	-Do-
07	Manganese Sulphate Mnso4	10819-019 2.4Kg	-Do-	-Do-

02. FID-III Islamabad vide letter No. F. 3-9/2010-FID-II (ISD) dated 15-09-2020 submitted as under;

"Undersigned has inspected the premises of M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No. 10, S-6, NIZ, RCCI Rawat, Islamabad on 10th October, 2019. During inspection following drugs were placed in warehouse of the firm premises due to the reason mentioned below in contravention of DRAP Act, 2012 under Drug Act, 1976 and rules framed ther under. Therefore the below mentioned drugs were ordered not to dispose off for 28 days under schedule -V Section (1) (i) of DRAP Act, 2012 read with section (18) (1)(i) of the Drugs Act, 1976.(Annex-A).

S.#	***Name of Drug***	***Batch & Quantity***	***Manufacturer***	***Reason***
1	*Invermectin*	*201808021 1.7Kg*	*Unknown*	*The firm's management is unable to provide the import authorization/ clearance document of material issued by (I&E) DRAP.*
2	*Bismuth*	*19030211 4.1 Kg.*	*-do-*	*-do-*
3	*Ferro Sulphate*	*00118-060 22.250Kg*	*-do-*	*-do-*
4	*Copper Sulphate*	*RLFX-873-18 19.90Kg*	*-do-*	*-do-*
5	*Zinc Sulphate*	*JXBHB2019-014 17.7Kg*	*-do-*	*-do-*
6	*Mangnesium Sulphate*	*Not know. 50Kg*	*-do-*	*-do-*
7	*Mangnesium Sulphate Mnso4*	*10819-019 2.4Kg.*	*-do-*	*-do-*

3. M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No. 10, S-6, NIZ, RCCI Rawat, Islamabad was directed vide this division letter of even number dated 14-10-2019 , subsequent reminder dated 02- 01-2020under drugs Act, 1976 and rules framed there under , as required under section 32 (3) (b) (i) (ii) of Drug Act, 1976 under DRAP Act, 2012. (Annex-C).

i. License/ permission certificate of said imported Raw Material.
ii. Clearance of Assistant director (I&E).
iii. Any written evidence of loan from another manufacturer

4. M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No. 10, S-6, NIZ, RCCI Rawat, Islamabad intimated that they purchased quantity of 2Kg of Ivermectin and 25 Kg of

Bismuth from local market to fulfill some urgent supply and presented or clarification about other drugs (photo copy enclosed) (Annexed-D)

5. It is pertinent to mention that the firm failed to provide any evidence as asked for about in the said letter, hence the firm contravened Section 23 (1) (d)(e) read with Section 27 (1) (C) and 27 (4) of the Drug act, 1976 and rule 7 & 15 (1) of drug import and Export Rules, 1976. Following persons are involved in the said contravention and action mentioned below are being purposed:-

i. Prosecution in the Drug Court.
ii. Cancellation/ suspension of registration of all the product where the said illegal raw material used.
iii. Cancellation/ suspension of DML of all the sections where the said illegal raw material used.

	Name	***CNIC#***	***Designation***
1	*Dr. Javed Saeed*	*37405-0357375-7*	*Chief Executive of the firm.*
2	*Mr. Zia Hussain*	*3706-5184938-7*	*Production incharge.*
3	*Mr. Ajmal Zaman*	*37405-0438707-1*	*QC incharge.*

6. Submitted for perusal under Section 19(7) to the competent authority as desired, please."

03. The case was presented before the Board in its **297th meeting** wherein it was decided as under:

"The Board after detailed deliberations and considering the facts of the case decided to issue show cause notice for cancelation/suspension of products to the accused."

04. In compliance to the decision of Registration Board, the accused was issued a show-cause notice vide No. F. 03-56/2021-QC (Pt-I) (297-RB) dated 05-04-2021. The accused has replied vide ref. No. HBP 4 / 2021 dated 15-04-2021 which is given as under:

"This refer to your letter no. F.03-56/2021-QC(Pt-I) (297-RB) dated April 05,2021 via ums services, which we received on dated April 12,2021 on Subject cited above.

- *Please provide us an opportunity to be heard in person in response to above show cause notice.*
- *We want to submit justification / clarification in person."*

05. Keeping in view of above-mentioned reply, the representatives of the firm are called before the Board for personal hearing.

06. Proceedings and decision of 307th meeting of Registration Board:

Dr. Javed Saeed (CEO M/s. Hawk Bio Pharma, Islamabad) along with QC Manager, Mr. Ajmal and Production Manager, Mr. Zia Hussain appeared before the Board for Personal hearing. They pleaded that they have submitted evidence to FID that their imports were done as per legal procedures. They submitted a written reply and supporting documents. The Board after considering the facts of the case and thorough deliberations decided as follows:

i. Refer the case back to area FID for complete investigation.
ii. Suspend all registered products of the firm (as identified by area FID) that were manufactured by the raw materials in question.

07. In compliance to the decision of 307th meeting of the Registration Board, letter vide No. No.F.03-15/2021-QC (307-RB) (Pt-I) dated 03-08-2021 was issued to M/s. Hawk Bio Pharma Islamabad and area FID Islamabad for submission of complete investigation report. Area FID Islamabad vide letter No. F. 2-10/2011-FID-II (ISD) dated 05-01-2021 submitted as under:

*"The then FID-III inspected the premises of M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No.10, S-6, NIZ, RCCI Rawat, Islamabad on 10th October, 2019. During inspection following drugs/materials were present in warehouse/RMS of the firm's premises. FID when asked about import authorization/clearance documents of these materials, the firm could not provide the same. The FID hence on contravention of DRAP Act, 2012 under Drug Act, 1976 and rules framed thereunder ordered Not to dispose of these materials under section schedule –V Section (1)(i) of DRAP Act, 2012 read with section (18)(1)(i) of the Drugs Act, 1976 (**Annex-A**).*

S.#	***Name of Drug***	***Batch & Quantity***	***Manufacturer***	***Reason***
1	*Invermectin*	*201808021 1.7Kg*	*Unknown*	*The firm's management is unable to provide the import authorization/ clearance documents*

				of material issued by (I&E) DRAP.
2	*Bismuth Subnitrate*	*19030211 4.1Kg.*	*-do-*	*-do-*
3	*Ferrous Sulphate*	*00118-060 22.250Kg*	*-do-*	*-do-*
4	*Copper Sulphate*	*RLFX-873-18 19.90Kg*	*-do-*	*-do-*
5	*Zinc Sulphate*	*JXBHB2019-014 17.7Kg*	*-do-*	*-do-*
6	*Magnesium Sulphate*	*Not mentioned on COA 50Kg*	*-do-*	*-do-*
7	*Manganese Sulphate*	*10819-019 2.4Kg*	*-do-*	*-do-*

*2. The case was submitted for the grant of permission for extension in period of ordered not to dispose of under schedule–V Section (1)(i) of DRAP Act, 2012 read with section (18)(1)(i) of the Drugs Act, 1976. The necessary approval of the competent forum regarding extension for further period under clause (i) of section (1) of schedule (V) read with section (18)(1)(i) of the Drug Act, 1976 was granted till 09th January 2020 and conveyed vide letter No. 13-195/2019-QC dated 30-12-2019 (**Annex-B**).*

*3. M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No.10, S-6, NIZ, RCCI Rawat, Islamabad was directed vide letter of even number dated 14-10-2019, subsequent reminder dated 02-01-2020 under drugs Act, 1976 and rules framed there under, as required under section 32(3)(b)(i)(ii) of Drug Act, 1976 under DRAP Act, 2012 for the provision of following **(Annex-C).***

i. Import document.
ii. Clearance of Assistant Director I&E.
iii. Import License &
iv. Record about source of import including test analysis.

*4. M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No.10, S-6, NIZ, RCCI Rawat, Islamabad submitted on 10.01.2020 that they purchased quantity of 2 Kg of Ivermectin and 25 Kg of Bismuth subnitrate from local market to fulfill some urgent supply and presented their or clarification about other drugs (**Annexed-D**).*

5. While investigation, the firm failed to provide any evidence regarding quires mentioned in the para 3/N hence the firm contravened Section 23(1)(d)(e)read with Section 27(1) (C) and 27(4) of the Drug act, 1976 and rule 7 & 15(1) of drug import and Export Rules, 1976. Following persons were involved in the said contravention and following actions were purposed:-

i. Prosecution in the Drug Court.
ii. Cancellation/ suspension of registration of all the product where the said illegal raw material used.
iii. Cancellation/ suspension of DML of all the sections where the said illegal raw material used.

S.#	***Name***	***CNIC#***	***Designation***
1	*Dr. Javed Saeed*	*37405-0357375-7*	*Chief Executive of the firm.*
2	*Mr. Zia Hussain*	*37406-5184938-7*	*Production incharge.*
3	*Mr. Ajmal Zaman*	*37405-0438707-1*	*QC incharge.*

6 The case was presented before the Board in its 297th meeting, wherein it was decided as under:

"The Board after detailed deliberations and considering the facts of the case decided to issue show cause notice on violation of Rule 7 and 15(1) of Drug (Import &Export) Rules, 1976 relevant provision of law for cancelation/suspension of products."

7. In compliance to the decision of Registration Board, the accused was issued a show-cause notice vide No. F.03-56/2021-QC (pt-I) (297-RB) dated 05-04-2021. In response, the accused replied vide reference No. HBP 4/2021 dated 15.04.2021 which is given as under:

"This refer to your letter no. F.03-56/2021-QC (Pt-I) (297-RB) dated April 05,2021 via ums services which was received on dated April 12,2021.

- *Please provide us an opportunity to be heard in person in response to above show cause notice.*
- *We want to submit justification/clarification in person"*

8. Keeping in view of above-mentioned reply, the representatives of the firm were called before the Registration Board in its 307th meeting of Registration Board on 10.06.2021 for personal hearing. The proceedings and decision of 307th meeting of Registration Board was as under:

"Dr. Javed Saeed (CEO M/s. Hawk Bio Pharma, Islamabad) along with QC Manager, Mr. Ajmal and Production Manager, Mr. Zia Hussain appeared before the Board for Personal hearing. They pleaded that they have submitted evidence to FID that their imports were done as per legal procedures. They submitted a written reply and supporting documents. The Board after considering the facts of the case and after thorough deliberations decided as follows:

i. Refer the case back to area FID for complete investigation.
ii. Suspend all registered products of the firm (as identified by area FID) that were manufactured by the raw materials in question.

10. In response to the decision of Registration Board taken in it's 307th meeting, the firm was called for investigation of case.

Investigation of Case:

The firm was asked to submit the evidence of loan & proof of import clearance by DRAP. In response they submitted the loan request applications alongwith inward, outward Gate Pass & GRN of Ivermectin & Bismuth Subnitrate alongwith import clearance documents & COAs of both loaned & self-imported materials ***(Annex-E)****. However, they could not provide the evidence of import of loaned material of Bismuth subnitrate. For which they have submitted that since they loaned it from M/s Mansoor Chemicals, Karachi who have informed them the given material was expired during 2020. Hence, they have disposed off the documents after expiry period* ***(Annex-F)****. Regarding Ferrous Sulphate, Copper Sulphate, Zinc Sulphate, Magnesium Sulphate and Manganese Sulphate, they have submitted clarification that these are considered as excipients. Hence no need of import authorization required. They have further informed that all the materials (except Magnesium Sulphate) have now been expired as details mentioned on COAs as per following details and they have hence requested for destruction of materials since the materials have been expired now and they shall be careful in future* ***(Annex-G)****:*

S.#	***Name of Drug***	***Batch & Quantity***	***Date of Expiry (As mentioned on COA)***	***Manufacturer***
1.	*Invermectin*	*201808021 1.7Kg*	*17th August 2020*	*Unknown*
2.	*Bismuth Subnitrate*	*19030211 4.1Kg.*	*27th October 2020*	*-do-*
3.	*Ferrous Sulphate*	*00118-060 22.250Kg*	*12th April 2018*	*-do-*
4.	*Copper Sulphate*	*RLFX-873-18*	*11th November 2020*	*-do-*

		19.90Kg		
5.	*Zinc Sulphate*	*JXBHB2019-014 17.7Kg*	*11th January 2021*	*-do-*
6.	*Magnesium Sulphate*	*Not mentioned on COA 50Kg*	*Not mentioned on COA*	*-do-*
7.	*Manganese Sulphate*	*10819-019 2.4Kg*	*11th May 2021*	*-do-*

11. In the light of above, it is concluded that the firm was involved in loaning practices which has no legal coverage. Regarding Ferrous Sulphate, Copper Sulphate, Zinc Sulphate, Magnesium Sulphate and Manganese Sulphate their clarification is not justified on scientific & legal grounds. The investigation of case and the request of firm for destruction of materials is submitted before Registration Board."

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board deferred the case for further deliberation in next meeting.

Case No. 24: IMPORT OF REGISTERED PRODUCTS THROUGH FAKE/FORGED INVOICES BY M/S. BIOCURE PHARMACEUTICALS, LAHORE.

01. Assistant Director (I&E), Lahore vide letter No.5247/2019/DRAP(AD-CD)(I&E) dated 15-04-2019 informed that Assistant Collector-II, Model Customs Collectorate of Appraisement-West, Karachi has asked for the verification of genuineness of following ADC invoices;

Sr. No	Invoice No. & Date	Diary No. & date	Dispatch No. & Date
1	SBF/EXP/23-2019, dated 21-02-2019	4699/2019 DRAP dated 15-03-2019	3769/2019-DRAP, dated 19-03-2019
2	SBF/EXP/24-2018, dated 15-03-2018	4569 dated 26-03-2018	4451/2018-DRAP, dated 29-03-2018
3	SBF/EXP/28-2017, dated 29-03-2017	5982 dated 27-04-2017	5647/2017-DRAP, dated 28-04-2017
4	SBF/EXP/127-2015, dated 28-10-2015	13579 dated 23-11-2015	18835/2015-DRAP, dated 26-11-2015
5	SBF/EXP/128-2016, dated 27-12-2016	1524 dated 26-01-2017	1396/2017-DRAP, dated 27-01-2017

02. AD (I&E), DRAP, Lahore further informed that the genuineness of the endorsement of said invoices is not verified from the office record. In response to the submission of AD (I&E), DRAP, Lahore the division of QA&LT directed the Area FID vide letter F. No.13-125/2019-(QC) dated 16-05-2019 to investigate the matter and after completing all the legal formalities, submit a comprehensive report including all the requisite documents along with documents from custom authorities, highlighting the nature of violation, fixing the responsibility (Names, Designations, complete addresses and copies of CNIC of accused person(s)) and comments/views on the response of accused, if any, on priority basis for consideration of the Board.

03. Area Federal Inspector of Drugs Lahore vide letter No.7011/2021-DRAP (L-IV) dated 07-05-2021 submitted the complete investigation report and the reply of accused as under:

"Please refer to Drug Regulatory Authority of Pakistan, Islamabad letter No. F. No. 13-125/2019 (QC) dated 16-05-2019 on the subject cited above, (copy attached Annex-1), and Model Custom Collectorate of Appraisement-West Custom House, Karachi letters Nos. SI/Misc/157/2017 Group-II dated 22-03-2019 and SI/Misc/157/2017 Group-II dated 01-04 2019 on the subject cited above (copies attached Annex-2&3), wherein it was informed that genuineness of the endorsement of commercial invoices (detail of which are below) was not verified from the office record of DRAP, Lahore (Copies of invoices are attached annex 4,5,6,7&8).

S. No.	*Invoice No & Date*	*Diary No. & date*	*Dispatch No, & Date*
1	*SBF/EXP/23-2019, dated 21-02-2019*	*4699/2019 DRAP dated 15-03-2019*	*3769/2019-DRAP, dated 19-03-2019*

2	*SBF/EXP/24-2018, dated 15-03-2018*	*4569 dated 26-03-2018*	*4451/2018-DRAP, dated 29-03-2018*
3	*SBF/EXP/28-2017, dated 29-03-2017*	*5982 dated 27-04-2017*	*5647/2017-DRAP, dated 28-04-2017*
4	*SBF/EXP/127-2015, dated 28-10-2015*	*13579 dated 23-11-2015*	*18835/2015-DRAP, dated 26-11-2015*
5	*SBF/EXP/128-2016, dated 27-12-2016*	*1524 dated 26-01-2017*	*1396/2017-DRAP, dated 27-01-2017*

2 Letter No. 12040/2019-DRAP (L-VI) dated, 17-09-2019, was sent from this office to M/s. Biocure Pharmaceuticals, Suite No. 211, 2nd Floor Khaleej Town, 38-A, Jail Road, Lahore, informing that genuineness of endorsement of said invoices was not verified from the office record and the firm was directed to explain their position in this regard (copy attached annex-9).

3 Reply received from M/s. Biocure Pharmaceuticals, Suite No. 211, 2nd Floor Khaleej Town, 38-A, Jail Road, Lahore vide letter No. Nil, dated Nil received office on 02-10-2019 (copy attached annex-10), wherein they have informed that after coming to know of the above they launched FIR against the clearing agent, whom they had hired some time ago (copy attached annex-11) The CEO of the firm further informed that he was shaken after knowing about this matter which caused severe tension, heart attack and cardiogenic shock. He has further requested that he may be granted relief on humanitarian basis. Previous import history of the firm as per this office record showing clearance certificates obtained from this office previously is also attached (copy attached annex-12). But as per available record of this office the above said invoices were not cleared by this office.

4 The available data of this office reveals that the firm did not get prior clearance to import their products Eridoksin Registration No. 059185 and Roxine 25% Registration No. 059186 which is the violation of the Drugs Act 1976/DRAP Act 2012, so, it is recommended that the registration of the drugs / product in question may be suspended or cancelled or any other action may be taken as deemed fit by the Competent Authorities.

Submitted for information and further necessary action please."

04. Area FID Lahore in the above-mentioned report has recommended the cancellation/suspension of registration of products namely Eridoksin powder containing Erythromycin 40mg and Doxycycline 20mg (Reg. No. 059185) and Roxine 25% oral solution containing Enrofloxacin 250g (Reg. No. 059186) or any other action as may deem fit by the Board.

Proceedings and Decision of 312th meeting:

05. The Board after thorough deliberations and considering the facts of the case and recommendations of the area Federal Inspector of Drugs decided to issue show cause notice to firm for cancellation/suspension of their registered product.

06. In compliance to the decision of 312th meeting of the Registration Board, the firm was issued show cause notice vide F.No.03-33/2021-QC (312-RB) dated 28-10-2021. Till date no reply has been received from the firm.

07. The representatives of the firm are called before the Board for personal hearing.

Proceedings and Decision of 313th meeting:

08. Jawad Ahmed (CEO) of M/s. Biocure Pharmaceuticals, Suite No. 211, 2nd Floor Khaleej Town, 38-A, Jail Road Lahore appeared before the Board and informed the Board that he had hired a clearing agent namely Muhammad Sadiq S/o Abdul Aziz R/o House No. 49-A, Street No. 139-C, Ittefaq street, Ghulam road, Ichhra Lahore who was responsible for submitting fake invoices to the custom authorities. Moreover, Mr. Jawad Ahmed also informed the Board that he was unaware of these illegal activities being carried out by his clearing agent and he also had lodged FIR against that clearing agent in Litton road Police Station Lahore.

09. The Board after thorugh deliberations, considering the facts of the case and submission of CEO of M/s. Biocure Pharmceuticals Lahore decided as under:

i. Suspend the Registration of the products namely Eridoksin Powder (Reg. No. 059185) and Roxine 25% oral solution (Reg. No. 059186) for (06) months.
ii. The division of QA&LT will conduct a detailed investigation of the matter and submit a comprehensive report before the Board within (02) months.

10. In the light of the decision of Registration Board, the accused were issued a letter for suspension of their products vide letter F. No. 03-43/2021-QC (313-RB) dated 16-12-2021. Moreover, brief facts of the case is given as under:

- Assistant Director (I&E), Lahore vide letter No.5247/2019/DRAP(AD-CD)(I&E) dated 15-04-2019 informed that Assistant Collector-II, Model Customs Collectorate of Appraisement-West, Karachi has asked for the verification of genuineness of ADC invoices as mentioned in table of para 01.
- The division of QA&LT directed the Area FID vide letter F. No.13-125/2019-(QC) dated 16-05-2019 to investigate the matter and submit a comprehensive report of the matter.
- Area FID Lahore informed that the invoices provided by the Assistant Collector-II, Model Customs Collectorate of Appraisement-West, Karachi are forged and the firm did not get prior clearance to import their products and recommended that the registration of the drugs / product in question may be suspended or cancelled.
- The Registration Board in its 312th meeting decided to issue Show cause notice and personal hearing to the management of M/s. Biocure Pharmaceuticals Lahore.
- Jawad Ahmed (CEO) of M/s. Biocure Pharmaceuticals of the firm appeared before the Board in its 312th meeting and submitted that he had hired a clearing agent namely Muhammad Sadiq S/o Abdul Aziz R/o House No. 49-A, Street No. 139-C, Ittefaq street, Ghulam road, Ichhra Lahore and the fake invoices were submitted by him. The said person is not traceable and Jawad Ahmad (CRO) of M/s. Biocure Pharmaceuticals Lahore had lodged FIR against that person in Litton road Police Station Lahore. A Copy of FIR is also submitted by the CEO of M/s. Biocure Pharmaceuticals Lahore.
- The invoices provided by Assistant Collector-II, Model Customs Collectorate of Appraisement-West, Karachi are dated 26-11-2015, 27-01-2017, 28-04-2017, 29-03-2018 and 19-03-2019 in her letter dated 15-04-2019 whereas the accused had lodged the FIR against his clearing agent on 22-06-2019.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

The Registration Board deferred the case for further deliberation in next meeting.

Case No. 25: ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S. EG PHARMCEUTICALS 13-A INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

Federal Inspector of Drugs-I Islamabad inspected the premises of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad on 25th January 2022 to investigate PM portal complaint regarding the import of illegal raw material, lack of qualified persons and non-compliance of GMP by M/s. EG Pharmaceuticals Islamabad. During the inspection following Raw Material was recovered from the Raw Material Store (RMS) of the M/s EG Pharmaceutical Islamabad without import documents/NOCs issued by DRAP R&I Section as well as evidence of purchase:

S.	Name of Drug	Batch No.	Quantity	Mfg. by
01.	Amlodipie Besylate powder	AMB/057/03/21	0.29kg	M/s. Prudunce Chemical
02.	Diclofenac Potassium	20190810	109.125	M/s. Zanghai Gindjiuzhou Pharma Henan Dongtai Pharma Co Ltd
03.	Diclofenac Sodium	20200520	3.135	N/A
04.	Tizanodium powder	N/A	2.50	N/A
05.	Ketorolac Trtonetamol/ Tronethamine	0361220	0.800	M/s. Satyalidivis Pharma
06.	Lidocaine HCl	N/A	0.804	N/A
07.	Metronidazole		13.000	N/A
08.	Paroxetine Calcium		1.000	N/A
09.	Rosuvastatine Calcium		36.0 gm	N/A
10.	Vitamin B3		3.10gm	N/A
11.	Valsartan		0.36	N/A
12.	Metformin	MEF/1010233	598.950	AARTI Begus Ltd India
13.	Loratidine	NRHB0534	5.000	Morepan Lab India
14.	Sitagliptin		3.734	N/A

02. The mentioned raw materials were ordered "Not to Dispose of' on Form-1 dated 25-01-2022 under schedule-V Section (l)(i) of DRAP Act 2012. Permission in order not to dispose of was granted to FID I Islamabad vide letter F.03-05/2021-QC dated 21st February 2022.

03. M/s. EG Pharmaceuticals Islamabad was directed by FID I to submit import documents/NOCs issued by the DRAP I&E Department or as well as evidence of purchase of the above-mentioned raw materials vide letter No. F. 03-07/2004-FID-I(ISD) dated 31st January, 2022 with subsequent reminders on 17th March 2022 and 13th April 2022. The firm replied vide letter dated 12th April 2022 and admitted that they are obtaining raw material on loan from the local manufacturers/local markets as they are producing their products in small quantities to fulfill institutional commitments and to avoid market shortage and hence small amount required did not warrant import.

04. In light of the firm's response, FID I Islamabad directed the firm vide letter No. F.03-07/2004-FID-I(ISD) dated 25th April 2022 to disclose the sources from which they had procured the above-mentioned raw material on loan in order to identify the culprits & to discourage such practices since it is violation of Import & Export rules 1976 & Section 23(l)(e) and punishable under Section 27(c) of the Drugs Act, 1976. The firm was further directed to provide complete information regarding batch sizes of the aforementioned items as well as the institutional orders placed with the firm. The firm has failed to respond till date and verbally the representatives of the firm refused to provide further cooperation in this matter.

05. Considering the circumstances mentioned above, FID-I Islamabad has concluded that the firm is in violation of Import & Export rules 1976 & Section 23(1)(e) of the Drugs Act, 1976 read with Schedule-II(1)(A)(x)(e) punishable under Section 27(c) of the Drugs Act, 1976 read with Schedule-III(l)(c) of the DRAP Act, 2012 and cognizable under Section 30(1)(a) of Drugs Act,1976 read with Schedule-lV (l)(a) of the DRAP Act, 2012, and has requested as under:

i. Cancellation of Registration of the above-mentioned products
ii. Cancellation of DML of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad
iii. Grant permission for prosecution M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad through its CEO Mr. Shaukat Hayat Khan and its QC manager Mr. Ihtisham-ul-Haq.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion and thorough deliberations decided as under:

i. **Import and export of raw materials does not fall under the mandate of Registration Board. Hence, the case is referred back to QA&LT Division to decide the case under the Drugs (import & Export) Rules, 1976 under Drugs Act, 1976.**
ii. **Recommendation of FID to cancel DML of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad pertains to Licensing Division. Hence the QA&LT Division is advised to forward the case to Licensing Division.**

Case No. 26: CLUSTER OF SERIOUS ADRs REPORT BY USE OF VISO-REM (REMDESIVIR) INFUSION MFG BY M/S. VISION PHARAMCEUTICALS ISLAMABAD IN BAHRIA HOSPITAL LAHORE.

The Additional Director, Pharmacy Services Division, DRAP vide letter No. 9-1/2022 PV (PS) dated 15-02-2022 informed regarding the reports of serious ARDs (infusion related hypersensitivity reaction) by use of Viso-Rem (Remdesivir) injection 100mg/20ml manufactured by M/s. Vision Pharmaceuticals (Pvt.) Ltd., Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Road, Islamabad from M/s. Bahria International Hospitals, Lahore.

02. The reported events by Bahria International Hospital include, tachycardia, fever, shivering, shortness of breath and flushing of the skin. As per the Food and Drug Administration's (FDA) label of Veklury (Remdesivir), hypersensitivity reactions, including infusion-related and anaphylactic reactions, have been observed during and following administration of Remdesivir; most of these occurred within one hour. These hypersensitivity reactions include all the instant reported events such as shivering, tachycardia, shortness of breath and fever that are reported by Bahria International Hospital. NPC has performed the causality assessment and classified these reactions to have possible relation with the drug.

03. Additional Director Pharmacy Services further added that infusion-related hypersensitivity reactions may provide a possible explanation: however, these reports are cluster in nature having similar adverse events, same drug and its batch and reported within a short period of time from the same place, which triggers suspicion of a quality problem therefore, a letter vide No. 13-25/2022-QC dated 15-03-2022 was issued to area FID Lahore and area FID Islamabad for sampling of batch in question of subject mentioned product for the purpose of test/analysis.

04. FID-I Islamabad vide file 3-4/2003-FID-I_(Vol-II)-P-001 dated 29-07-2022 forwarded the complete investigation and inspection report of M/s. Vision Pharmaceuticals Islamabad, details of which are as under:

"In compliance of letter F.No.9-1/2022 PV (PS) dated 15th February 2022 regarding cluster of ADRs reported with Inj. Viso-Rem (Remdesivir 100mg/20ml Batch # 21H032) from Bahria International Hospitals, Lahore, the following panel visited M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad DML No. 000517 by way of Formulation:

1. *Mr. Hasan Afzaal, Assistant Director, QA&LT Division, DRAP, Islamabad*
2. *Mr. Tahir Waqas, Assistant Director, I&E section QA&LT Division, DRAP, Islamabad*
3. *Ms. Saadia Mahwish Area FID-I, DRAP, Islamabad*

The focus of the inspection was to investigate probable cause of the ADR reported in Batch# 21H032 of product Inj. Viso-Rem 100mg/20ml (in solution form). During the visit following representatives of the firm were present during investigation

1.Mr. Waseem Shehzad, Head Quality Operations
2.Mr. Nadeem Panjatan Chief Operating Officer/ Production Incharge
3.Mr. Shaukat Iqbal Quality Control Manager
4.Col. (R) Naveed Akbar, Director Operations
5.And other technical personnel including the Microbiologist

Following are the observations made by the panel during the course of the investigation.

i. The document retrieval time as agreed by the firm at the start of the inspection was supposed to be 30 minutes. However, the firm could not abide by the agreed upon timeline, sometimes by a margin of several hours and in some cases, by failing to provide the requisite documents at all.
ii.The firm did not have a formal Pharmacovigilance program in place either in document form or in practice. The sole reliance of the firm was on feedback gathered by their marketing team, who had not been provided with appropriate documentation or any SOPs on gathering information on and reporting of ADRs to their management. This observation was corroborated by the fact that the firm had no knowledge or record of ADRs occurring in the Bahria International Hospital.
iii. The firm was asked to provide the distribution record as well as Batch manufacturing record (BMR) of Inj. Remdesivir Batch# 21H032 and it was observed that firm had distributed 1806 vials to their authorized distributors in various cities. However, when the BMR of the concerned batch was examined, the actual yield of the product was calculated to be 2844 vials. When the firm was asked to provide the distribution record for the rest of the vials it was discovered that they had supplied 1000 vials to D.Watson pharmacy which is a violation of conditions of Registration/Emergency Use Authorization (EUA) letter No.F.5-3/2020-Reg-II (M-295) dated 30th July 2020, the very first condition of which states that
"Registration of Remdesivir is authorized for emergency use only and for exclusive supply to healthcare facilities dealing with the COVID-19 patients under strict supervision of a qualified specialist physician"
iv. The firm was found to be in violation of other conditions of the above-mentioned letter of Registration/EUA as well namely:

a. *Viso-Rem Solution for Infusion had been granted Registration/EUA on Innovator's Specifications, however when the Certificate of Analysis of the product attached in the BMR of batch# 21H032 was studied, it was found that the testing had been carried out by the firm on in-house specifications, which is a violation of condition "x" of Registration/EUA letter. When the representatives of the firm were questioned regarding the matter, it appeared that the firm was under the impression that the terms "Innovator's Specifications" & "In-house Specifications" can be used interchangeably. The firm was unable to provide the CTD dossier for Inf. Viso-Rem nor did they provide any evidence of technology transfer from innovator. Henceforth, the panel could not determine the rationale behind the setting of specification limits*

for BET (Bacterial Endotoxin Test), pH, osmolarity, infusion volume and route of administration which may or may not have an association with the ADRs in question.

b. *As per condition "d" of above-mentioned Registration/EUA letter the firm was supposed to perform product development, process validation and concurrent real time & accelerated stability study of drug product for the first three commercial batches as per Zone IV-A climatic conditions. The testing frequency was supposed to be on monthly basis for the initial six months. On examination of the available record it was observed that the firm had not conducted stability studies on monthly basis, rather stability testing was carried out at 0, 3 & 6 months thus violating the condition of Registration/EUA. Furthermore, stability data sheet SOR 03644 states as a footnote that the product is stable for 06 months when kept at 2-8 °C, whereas the company is claiming shelf life of one year, when questioned, the Firm's representatives declared it to be a typographical error.*

c. *As per condition "h" of the Registration/EUA letter, although the firm had been submitting monthly reports to the National Pharmacovigilance Centre, in which they had been continually informing that there weren't any reports of occurrence of ADRs, however, this statement of the firm did not seem to be evidence based as they did not have any formal system of collecting information regarding ADRs also evidenced by the fact the firm was clueless about the ADRs reported from Bahria Hospital, Lahore.*

v. As stated previously regarding delay in document retrieval, the firm was unable to provide studies on the Qualification of area, equipment & personnel in support of the process validation studies shared with the panel. Furthermore, reference to the process validation the firm was unable to provide sufficient data/rationale in support of their use of non-sterile API as the process of sterilization relied only on one step Filtration for which the requisite Filter integrity test was only performed for product solution & not for filter cartridge used for double distilled water for vial washing & nitrogen used for purging. Additionally, the sterility test for Nitrogen is carried out on monthly basis & firm was unable to provide validation data for sterilization of compressed air. In addition to above, the area monitoring protocols require major revision as firm is performing reduced testing without any justification for area monitoring i.e., the frequency, exposure duration, incubation time & no of requisite plates/media is not in line with the acceptable International practices such as WHO TRS 961 in conjunction with ISO 14644. Also, inappropriate swabs were being utilized (not lint free) without swab recovery studies.

vi. The firm had conducted media fill trial of the facility once per annum (not-withstanding the guideline recommends bi-annual media fill trial). The incubator facility for media fill batch was not adequate hence the incubation was done at room temperature which did not suffice for the purposes of this test.

vii. During review of process validation studies, the panel was of the opinion that CPPs could have included critical points such as integrity test for filter at various steps, in-process sampling for BET, in process sterility testing for Bulk solution & post filling remnant solution, post filling swab test of contact parts as the firm had not deployed sterilization bags for detachable/sterilizable contact parts. Additionally, validation of disinfectant in conjunction with Bioburden profiling of the area was not shared with the panel despite request. The process capability index (CPI) for the validation process had not been calculated. To summarize the above observations pertaining to GMP, the sole reliance of the firm was on sterility testing of the finished product without scientific rationale of the sampling procedure i.e., identification of worst-case scenario such as collection of sample from identified cool points of the equipment as well as from beginning, middle, end etc. of the sterilization cycle. Additionally, the firm had failed to calculate the Sterility assurance level (SAL) of the sterilization process.

viii. Review of the Change control data showed that process validation studies had initially been carried out on 30L batch size. When the log of Change Control was examined it was found out that the firm had increased the batch size to 120L. However, according to document bearing Change Control No. CC/010/21 dated 12.08.2021 the description of the proposed change stated Viso-Rem Inj batch size increased from 60L to 120 L. No documentary record or change control procedure or scale-up study was however available for the increase of batch size from 30L to 60L. Furthermore., no risk analysis/impact analysis was performed in the change control document for increasing the batch size from 60L to 120L. The Change Control document also stated the process re-validation studies needed to be performed which till date had not been conducted by the firm.

ix. The firm has no system in place to review the data logged during cold chain transfer of Inj. Viso-Rem, hence temperature excursion/deviation can go unnoticed. No data logging review during cold chain transport was available for perusal.

x. The Certificate of Analysis (COA) of finished product in BMR of Inj. Viso-Rem did not record the results of Liquid Particle Counter (LPC) but when LPC log book was reviewed the test had been performed for the said batch. However, the exclusion of result of LPC test record from the BTR can lead to unnoticed deviation during batch release & exhibits poor documentary control for the firm.

xi. When the Batch processing record of Inj. Viso-Rem Batch# 21H032 was reviewed it was observed that the API (Remdesivir) utilized in the manufacturing was bearing Supplier batch #21051601 and the internal QC lot# 2106R0014. However, when the firm was asked to provide NOC for the said raw material issued by I&E department of DRAP, the firm provided documents of a different batch of same API i.e., Supplier batch #21041601 and the internal QC lot# 2105R0019 but the NOC issued by DRAP against this batch# was meant for semi basic manufacturing of Lyophilized Remdesivir and not for the manufacturing of the finished product. Later on, the firm provided documents including NOC issued by DRAP for batch# 21051601 QC lot# 2106R0014. When the certificates of Analysis of both batches were reviewed it was noticed that there was no difference in specifications and analytical results of both categories of APIs i.e. for semi basic manufacturing & for the manufacturing of finished product. Both batches had been manufactured and supplied by the same manufacturer i.e., Anhui Haikang Pharmaceutical Co., Ltd. The firm could not provide DMF on Remdesivir API. Therefore, the panel could not determine whether there is any significant difference in critical Quality Attributes including physical characteristics/composition between the Ready to Formulate API & the semi-basic raw material of Remdesivir. Furthermore, it could not be determined due to the reasons mentioned above whether mix-up between the two forms will impact the final finished product which may or may not reflect in batch testing report and also on patients' safety.

xii. The above-mentioned observations also point towards a total lack of Quality Management System in the firm including documentation control, Vendor Qualification & lack of User Specs/understanding of CQAs of raw materials to be procured for different manufacturing activities.

4. In pursuance of above-mentioned letter from Division of Pharmacy Services, samples of Viso-Rem Solution for Infusion were taken for the purpose of test/analysis on Form 3 including the batch in question i.e., 21H032 (copy attached). However, it is pertinent to mention that in accordance with WHO TRS 961 Annex 6 "Good Manufacturing Practices for Sterile Pharmaceutical Products" which states

"2.2 The sterility of the finished product is ensured by validation of the sterilization cycle in the case of terminally sterilized products, and by "media-fills" runs for aseptically processed products. Batch processing records and, in the case of aseptic processing, environmental quality records, should be examined in conjunction with the results of the sterility tests. The sterility test procedure should be validated for a given product. Pharmacopoeial methods must be used for the validation and performance of the sterility test.

2.3 For injectable products, the water for injection and the intermediate and finished products should be monitored for endotoxins, using an established pharmacopoeial method that has been validated for each type of product".

A standard test report cannot be a final determinant regarding quality of a product based on Quality by Design principle.

5. Based on the areas inspected, people met, the documents reviewed and considering the complete lack of Quality by design concept and the sole reliance of the firm on sterility & BET testing which itself does not comply with the International Guidelines in addition to other findings of the inspection team, i.e. failure of regulatory compliance & probability of mix up of raw material meant for semi-basic manufacturing with that of API meant for Finished product, it is the opinion of the panel that the absence of requisite validations & processes may have impacted the final product. The firm is hence liable to manufacture products which could have probably caused the observed ADRs. It is therefore recommended that RB may be requested to review the grant of Emergency use authorization for the product Viso-Rem Solution for Infusion manufactured by M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad and advise the firm to halt production of Viso-rem Injection till rectification of all the above-mentioned critical deficiencies.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion and thorough deliberations decided to refer the case to Pharmacy Services Division for reviewing the matter in Pharmacovigilance Risk Assessment Committee and submission of recommendations to Registration Board for its consideration and decision.

Case No. 27: CANCELLATION/SUSPENSION OF REGISTRATION OF WATER FOR INJECTION 2ml (REGISTRATION NO. Q24873) MANUFACTURED BY M/S AMSON VACCINES PHARMA (PVT) LTD, PLOT #154, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.

FID I Islamabad along-with Assistant Director QA-I, inspected the premises of M/s Amson Vaccines & Pharma (Pvt)Ltd 113 Industrial Triangle Kahuta Road Islamabad on 16th June 2022 to review the GMP compliance of the firm. During the course of inspection, the panel came to know that the firm is carrying out manufacturing of the subject mentioned product whereas they do not have approved section for manufacturing of the said item i.e. Liquid Injectable Vial-SVP (general) from the CLB. Chairman CLB vide letter no. F.l-26/94-Lic(PtVol-I) dated 30th June allowed renewal of tablet section (General), Capsule section (General), Oral Liquid section (General), Liquid Ampoule injection (vaccine), Liquid vial injection (Vaccine / Sera) Dry powder injection (Steroid), Quality control Laboratory and warehouse.

02. FID I reported that the firm is currently manufacturing their Water for Injection in the Vaccine facility. Moreover, the filling of WFI is being done on the same filling machine as their other vaccines without undertaking Cleaning validation as for all of these vaccines limit of detectability is not available.

03. The firm is utilizing their water for Injection only for inclusion as reconstitution medium in their product Inj. Hyzonate (powder for reconstitution) whereas the Registration letter of Inj. Hyzonate does not specifically mention that only WFI manufactured by M/s Amson Vaccines & Pharma has to be included.

04. After the subject mentioned inspection, the firm submitted letter No. F. l-26/94-Lic(Pt-l) dated 14th December 2021 regarding Approval of layout plan for regularization/revised/new sections under DML No. 000393 (Formulation) issued by the Licensing wherein approval for Tablet (Psychotropic), Liquid injectable Vial-SVP, Dry powder for injection (Steroid), Quality control lab and Warehouse. Additionally, the firm submitted an undertaking that they will finish construction of Liquid Injectable Vial-SVP (general) within one year which clearly indicates without a doubt that as of right now the firm does not have approved section for manufacturing of Water for injection 2ml registration No.024873.

05. FID I reported that the panel advised the firm that they should get Approval of Liquid Injectable Vial-SVP (general) for manufacturing of Water for Injection in the existing facility in the interim period till construction/completion of the new building, the feasibility of which had been pointed/laid out to the firm in the closing meeting of the inspection. The firm however, point blank refused to consider the possibility even though it was made clear to the firm that they are undertaking an illegal activity. Furthermore, the firm was verbally directed to immediately stop production until the approval of Liquid Injectable Vial-SVP (general) from CLB, the firm however, adamantly and willfully refused to comply with the instructions and insisted on illegal manufacturing whereby, the firm stands in obstruction of Power of the Inspector granted under Section 18(l)(j) & punishable under Section 27(3) of Drugs Act,1976 read with Schedule-Ill (3) of DRAP Act, 2012

06. Keeping in view the above-mentioned facts of the case, FID I has recommended following actions against M/s. Amsons Vaccine and Pharma Islamabad:

i. Cancellation/Suspension of Registration of Water for injection 2ml registration No.024873 until the firm either completes the new building or gets section approval from CLB in the existing facility since as of today the firm M/s Amson Vaccines & Pharma (Pvt) l td do not have the requisite section approval from CLB

ii. Permission for prosecution against M/s Amson Vaccines & Pharma (Pvt) Ltd plot# 154 Industrial TriabngleKahuta Road, Islamabad through its management Mr. Abbas Khan S/O Dilawar Khan, Mr. Shamim Ahmad S/O Abdul Majeed. Mr. Saleem Asghar S/O Ali Sagheer, its Plant Manager Mr. Amanullah Sial, its Production In-charge Mr. Sajjad Hussain S/O M. Bashir & bits QC Incharge Mr. MuammadMuddassir S/O Noor Muhammad under Section 27(3) of Drugs Act, 1976 read with Schedule-Ill (3) of DRAP Act, 2012.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion, considering the facts of the case decided:

i. "To issue show cause notice to M/s. Amson Vaccines & Pharma (Pvt) Ltd, Islamabad for suspension/cancellation/ prosecution in Drug Court,

Islamabad for manufacturing of Water for injection 2ml registration No.024873 in vaccine manufacturing facility and called them for personal hearing before Registration Board as per clause 5.2 of Schedule B under Drugs (L, R & A) Rules, 1976.

ii. Advised to proceed as per Section 27 (3) of Drugs Act, 1976 regarding obstruction in official duties as it does not pertain to Registration Board."

AGENDA ITEM NO. 04
CASES REFERED BY QCB ISLAMABAD

Case No. 28: SUBSTANDARD GENTAMYCIN EAR DROPS MANUFACTURED BY M/S. AMROS PHARMA KARACHI – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/723 dated 22-02-2022 forwarded the case of manufacturing of Substandard Gentamycin 10ml Ear Drops Manufactured by M/s. Amros Pharmaceuticals Karachi. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of main store of DHO Office Islamabad drew samples of Gentamycin 10ml Ear drops B. No. EAM-011 manufactured by M/s. Amros Pharmaceuticals Karachi for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Gentamycin Ear drops as "Substandard" on the basis of pH.
iii. M/s. Amros Pharmaceuticals Karachi requested to challenge the results of DTL test report in NIH Islamabad. The appellate laboratory, NIH Islamabad also declared the Gentamycin 10ml ear drops as of "substandard" quality on the basis of pH and volume.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

> *"The Board was briefed about the facts of the case as per record by Secretary. The Board was also informed that the nominated accused did not appear. The Board considered the facts available on record and after discussion decided to refer the case to Drug Registration Board for cancellation of drug registration of i.e. Ear Drops Gentamycin manufactured by M/s. Amros Pharmaceuticals Karachi after fulfilment of all legal/codal formalities in this regard."*

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of Gentamycin 10ml Ear Drops, Reg. No. 019368 manufactured by M/s. Amros pharmaceuticals Karachi.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion, considering the facts of the case decided:

"To issue show cause notice to M/s. Amros pharmaceuticals Karachi for manufacturing and sale of substandard "Gentamycin 10ml Ear drops B. No. EAM-011" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

Case No. 29: SUBSTANDARD MULTIVITAMIN SYRUP B. NO. J19:018 MANUFACTURED BY M/S. NAWABSONS LABORATORIES, JIA BAGGA OFF RAIWIND ROAD, LAHORE – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/726 dated 22-02-2022 forwarded the case of manufacturing of Substandard Multi Vitamin Syrup 120ml Batch No. J19:018 Manufactured by M/s. Nawabsons Laboratories Lahore. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of District Population Welfare office G-9 markaz Islamabad drew samples of Multi Vitamin Syrup 120ml Batch No. J19:018 manufactured by M/s. Nawabsons Laboratories Lahore for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Multi Vitamin Syrup as "Substandard" on the basis of assay.
iii. The accused were called before Quality Control Board Islamabad in its 50th meeting but no one appeared before the Board.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

"The nominated accused did not appear before the Board. The Board considered the facts available on record and decided to refer the case to the Drug Registration Board for cancellation of registration of drug i.e. Syp. Multi Vitamin of M/s Nawabsons Laboratories, Lahore after fulfillment of all legal formalities in this regard."

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of Syp. Multi Vitamin 120ml, Reg. No. 004929 manufactured by M/s. Nawabsons Laboratories Lahore.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion, considering the facts of the case decided:

"To issue show cause notice to M/s. Nawabsons Laboratories Lahore for manufacturing and sale of Substandard product "Multi Vitamin Syrup 120ml Batch No. J19:018" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

Case No. 30: SUBSTANDARD MENTIN FORTE TABLET MANUFACTURED BY M/S. UNEXO LABS LAHORE – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/722 dated 22-02-2022 forwarded the case of manufacturing of Substandard Mentin Forte tablet Batch No. MT80 Manufactured by M/s. Unexo Labs (Pvt.) Ltd., Lahore. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of District Population Welfare office G-9 markaz Islamabad drew samples of Mentin Forte 625mg tablet Batch No. MT80 manufactured by M/s. Unexo Labs Lahore for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Mentin forte tablet as "Substandard" on the basis of assay.
iii. The accused were called before Quality Control Board Islamabad in its 50th meeting but no one appeared before the Board.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

"The nominated accused did not appear before the Board. The Board considered the facts available on record and decided to refer the case to the Drug Registration Board for cancellation of registration of drug i.e. Tab Mentin Forte (Co Amoxiclav) of M/s Unexolabs, Lahore after fulfillment of all legal formalities in this regard."

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of tablet Mentin Forte, Reg. No. 023923 manufactured by M/s. Unexolabs Lahore.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion, considering the facts of the case decided:

"To issue show cause notice to M/s. Unexolabs Lahore for manufacturing and sale of Substandard product "Mentin Forte tablet Batch No. MT80" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

Case No. 31: MISBRANDED BALINGO INJECTION B. NO. BL-1417 MANUFACTURED BY M/S. BAJWA PHARMACEUTICALS (PVT.) LTD., 36-KM OFF G.T ROAD LAHORE – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/725 dated 22-02-2022 forwarded the case of manufacturing of Misbranded Injection Balingo 10ml (Lignocaine) Batch No. BL-1417 Manufactured by M/s. Bajwa Pharmaceuticals, Lahore. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of District Population Welfare office G-9 markaz Islamabad drew samples of injection Balingo 10ml Batch No. BL-1417 manufactured by M/s. Bajwa Pharmaceuticals Lahore for the purpose of test/analysis.

ii. DTL Rawalpindi declared the said batch of Injection Balingo 10ml as "Misbranded" under clause (vi) of subsection (s) of section 3 of the Drugs Act 1976.
iii. The accused were called before Quality Control Board Islamabad in its 50th meeting for personal hearing.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

> *"The Board was briefed about the facts of the case as per record by the Secretary. The representative of firm alongwith supplier appeared before the Board and informed that the labeling error was rectified and replacement to the Department was also made. The members also questioned the representative about the existence of Quality Assurance arrangements of the firm.*
> *The Board considered the facts available on record and after discussion decided to refer the case to Drug Registration Board for cancellation of drug registration of i.e. Inj. Balingo 10ml of M/s Bajwa Pharmaceuticals, Lahore after fulfillment of all legal/codal formalities in this regard"*

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of Injection Balingo 10ml, Reg. No. 078952 manufactured by M/s. Bajwa Pharmaceuticals Lahore.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion, considering the facts of the case decided:

> **"To issue show cause notice to M/s. Bajwa Pharmaceuticals Lahore for manufacturing and sale of Misbranded Injection Balingo 10ml (Lignocaine) Batch No. BL-1417" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."**

Case No. 32: SUBSTANDARD METRONIDAZOLE 400MG B. NO. 597 MANUFACTURED BY M/S. NAWABSONS LABORATORIES, JIA BAGGA OFF RAIWIND ROAD, LAHORE – QCB ISLAMABAD CASE.

01. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/724 dated 22-02-2022 forwarded the case of manufacturing of Substandard Metronidazole tablet Batch No. 597 Manufactured by M/s. Nawabsons Laboratories Lahore. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of District Population Welfare office G-9 markaz Islamabad drew samples of Metronidazole tablet Batch No. 597 manufactured by M/s. Nawabsons Laboratories Lahore for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Metronidazole tablet as "Substandard" on the basis of disintegration.
iii. The accused were called before Quality Control Board Islamabad in its 50th meeting but no one appeared before the Board.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

> *"The nominated accused did not appear before the Board. The Board considered the facts available on record and decided to refer the case to the Drug Registration Board for cancellation of registration of drug i.e. Tab Metronidazole 400mg of M/s Nawabsons Laboratories, Lahore after fulfillment of all legal formalities in this regard."*

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of registration of Metronidazole tablet, Reg. No. 014336 manufactured by M/s. Nawabsons Laboratories Lahore.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion, considering the facts of the case decided:

> **"To issue show cause notice to M/s. Nawabsons Laboratories Lahore for manufacturing and sale of Substandard product "Metronidazole tablet Batch No. 597" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for**

suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

Case No. 33: SAMPLES NOT TESTED DUE TO TECHNICAL CONSTRAINTS

FID I Peshawar has submitted vide No. F. 3-20/2021-DRAP-4842 dated 16-12-2022:

" Kindly refer to above cited subject and to say that this office has received test report (Form-6) from the Federal Government Analyst, Central Drugs Laboratory with the following remarks;

i. Sample could not be tested due to technical constraint at present.

2. It is requested that the firms are directed to comply the requirements of CDL, Karachi as and when correspondence is received from CDL, Karachi in the said matter. However, after receipt of Form-6 with the above reffered remarks, further course of action is not defined/specified. It is requested that necessary directives/ guidlines may please be issued to undersigned for further course of action, in such matters to finalize the case."

Following are the details of reports provided by FID, Peshawar:

S. No.	Name of Product	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Claimed to be manufactured by	Report No. and Date	Remarks of CDL
01	IB-Clar Suspension (Clarithromycin)	085051	D-335	06-21	06-23	M/s. Iceberg Pharmaceuticals, Pisalpur.	IP.65/2021 dated 10-09-2021	Sample could not be tested due to technical constraint at present.
02	Essonave Capsules (Esomeprazole Magnesium)	077407	508	05-21	04-23	M/s. Novae Pharmaceuticals, Hattar	IP.30/2021 dated 17-08-2021	Sample could not be tested due to technical constraint at present.
03	Zee-Met Infusion (Metronidazole)	076873	2106843	06-2021	05-2023	M/s. Shazeb Pharmaceutical Industries Ltd., District Haripur.	IP.52/2021 dated 17-08-2021	Sample could not be tested due to technical constraint at present.
04	Zolan Suspension (Metronidazole Diloxanide Furoate)	027683	L016	06-21	06-23	M/s. Swat Pharmaceuticals, Saidu Sharif Swat.	IP.60/2021 dated 10-09-2021	Sample could not be tested due to technical constraint at present.
05	CB-Get Suspension (Cefixime)	085224	D-346	06-21	06-23	M/s. Iceberg Pharmaceutical, Risalpur.	IP.64/2021 dated 10-09-2021	Sample could not be tested due to technical constraint at present.

A letter has been issued to Federal Government Analyst vide letter F.No.13-27/2022-QC dated 14-03-2022 to provide the reason of "Samples could not be tested due to technical constraint at present."

Federal Government Analyst vide No. 1-1/2013-SRK/CDL/-1120 dated 19-04-2022 submitted following reasons due to which samples could not be tested:

1. The laboratory staff was busy in preparation and conduct of WHO Pre-qualification audit.
2. The risk with not carrying the tests on the referred samples was low as these samples were not taken by the inspectors due to issues of compliance or reports of adverse effects or complaints.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion and considering the facts of the case decided:

"To advise Federal Government Analyst, Central Drugs Laboratory, Karachi to test/analysis the samples in question and submit the report within 60 days to FID concerned for necessary action into the matter under intimation to QA&LT Division."

Item No. V: Additional Agenda

a. *Pharmaceutical Evaluation & Registration Division*

Item No. 1: Cases of Paracetamol containing formulations

DRAP Authority in its 147th meeting decided as under:

"In order to ensure the smooth and continuous supply of paracetamol tablets across Pakistan under prevailing circumstances, the Authority, as one-time exercise, approved incentivization to the manufacturers in the form of out-of-queue consideration of applications of registration of:

i) 01 generic (me-too) molecule on manufacturing and immediate distribution of at least 15,000 packs of paracetamol tablets with pack size of 200 tablets.

ii) *All dosage forms of paracetamol & its combination products with the condition of immediate manufacturing and distribution.*

Accordingly following cases have been evaluated and are placed before the Board

Cases of applications submitted on Form 5

Agenda of Evaluator PEC-III

1.	**Name and address of manufacturer / Applicant**	**M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Saypol CF Tablet 500/60/4mg
	Composition	Each Tablet Contains: Paracetamol…500mg Pseudoephedrine HCl…60mg Chlorpheniramine Maleate…4mg
	Diary No. Date of R& I & fee	Dy No. 15335: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Panadol CF Tablet by GSK
	GMP status	Last inspection dated 13-02-2018 confirms good level of GMP compliance.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of required manufacturing facility / section from Licensing Division DRAP. • Last GMP inspection report of the firm conducted within a period of last 3 years.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2.	**Name and address of manufacturer / Applicant**	**M/s Nortech Pharmaceuticals Plot #203,Sihala Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Tetsin Plus Tablet 37.5/325mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl…37.5mg Paracetamol…325mg
	Diary No. Date of R& I & fee	Dy No. 15418: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	(**MHRA** Approved)
	Me-too status	Tramal Plus Tablet by Searle
	GMP status	Renewal of DML report dated 20-09-2021
	Remarks of the Evaluator[3].	• Firm has applied in house specs while product monograph is available in USP.

	Decision: Approved with USP specifications. Registration Board further decided that registration letter will be issued after submission of fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
3.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Davigesic Tablet
	Composition	Each Film Coated Tablet Contains: Paracetamol…450mg Orphenadrine citrate……35mg
	Diary No. Date of R& I & fee	Dy No. 15877: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	(**TGA Australia** Approved)
	Me-too status	Nuberol Tablet by Searle
	GMP status	Renewal of DML report dated 20-09-2021
	Remarks of the Evaluator[3].	• Firm has applied for film coated tablet while the reference product approved by TGA Australia is as uncoated tablet, revise your formulation as per reference product along with submission of requisite fee. • Last GMP inspection report of the firm conducted within a period of last 3 years.
	Decision: Approved with innovator's specifications as per following details: • **To revise the formulation from film coated to uncoated tablet alongwith submission of fee as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.** • **Submission of GMP inspection report valid within last three years.** • **Label claim:** **Each tablet contains:** **Paracetamol……..…450mg** **Orphenadrine citrate……35mg**	
4.	**Name and address of manufacturer / Applicant**	**M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Orphamol 650/50mg Tablet
	Composition	Each Film Coated Tablet Contains: Paracetamol…650mg Orphenadrine citrate……50mg
	Diary No. Date of R& I & fee	Dy No. 16368: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nuberol Forte Tablet by Searle
	GMP status	GMP certificate issued on 15-11-2019 on the basis of inspection conducted 15-11-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Last GMP inspection report of the firm conducted within a period of last 3 years.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
5.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Tramacute P 37.5/325mg Tablet

	Composition	Each Tablet Contains: Tramadol HCl…37.5mg Paracetamol…325mg
	Diary No. Date of R& I & fee	Dy No. 16066: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	(**MHRA** Approved)
	Me-too status	Tramal Plus Tablet by Searle
	GMP status	The firm was inspected on 25-03-2019 and Conclusion of inspection was: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of inspection M/s Trigon Pharmaceuticals Pvt Ltd Lahore was considered to be operating at a satisfactory level of GMP compliance with reference to GMP guidelines as per Dugs Act, 1976 and rules framed there under.
	Remarks of the Evaluator[3].	• Firm has applied in house specs while product monograph is available in USP, revise your specification along with submission of requisite fee. • Firm has applied for uncoated tablet while the MHRA approved reference product is available as film coated tablet, revise your formulation along with submission of requisite fee. • Last GMP inspection report of the firm conducted within a period of last 3 years.
	Decision: Approved with USP specifications as per following details: • **To revise the formulation from film coated to uncoated tablet alongwith submission of fee as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.** • **Submission of GMP inspection report valid within last three years.** • **Label claim:** **Each film coated tablet contains:** **Paracetamol……325mg** **Tramadol HCl……37.5mg**	
6.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Max care 250mg/37.5/5mg/5ml Oral Solution
	Composition	Each 5ml Contains: Paracetamol…250mg Dextromethorphan hydrobromide…37.5mg Promethazine HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 16098: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 25-03-2019 and Conclusion of inspection was: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of inspection M/s Trigon Pharmaceuticals Pvt Ltd Lahore was considered to be operating at a satisfactory level of GMP compliance with reference to GMP guidelines as per Dugs Act, 1976 and rules framed there under.
	Remarks of the Evaluator[3].	• The label claim submitted by the firm does not contain Paracetamol, while the annexures submitted along with Form 5, covering letter and fee slip contains paracetamol. Revise your label claim along with submission of requisite fee.

		• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Last GMP inspection report of the firm conducted within a period of last 3 years.
	Decision: Deferred for submission of following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
7.	**Name and address of manufacturer / Applicant**	**M/s Libra Pvt Ltd 77-Peshawar Industrial Estate, Hayatabad Peshawar**
	Brand Name +Dosage Form + Strength	Orfenamol Tablet
	Composition	Each Tablet Contains: Orphenadrine citrate…35mg Paracetamol…450mg
	Diary No. Date of R& I & fee	Dy No. 16907: 07-03-2019 (ORIGINAL APPLICATION) Dy No. 26337: 19-09-2022 (DUPLICATE DOSSIER) PKR 20,000/-: 07-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	(**TGA Australia** Approved)
	Me-too status	Nuberol Tablet by Searle
	GMP status	GMP certificate dated 14-12-2020 issued on the basis of inspection dated 12-08-2020.
	Remarks of the Evaluator[3].	
	Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of fee that is Rs. 7,500/- for pre-registration variation fee as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
8.	**Name and address of manufacturer / Applicant**	**M/s Libra Pvt Ltd 77-Peshawar Industrial Estate, Hayatabad Peshawar**
	Brand Name +Dosage Form + Strength	Orfenamol Forte tablet
	Composition	Each Tablet Contains: Orphenadrine citrate…50mg Paracetamol…650mg
	Diary No. Date of R& I & fee	Dy No. 16906: 07-03-2019 (ORIGINAL APPLICATION) Dy No. 26336: 19-09-2022 (DUPLICATE DOSSIER) PKR 20,000/-: 07-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nuberol Forte Tablet by Searle
	GMP status	GMP certificate dated 14-12-2020 issued on the basis of inspection dated 12-08-2020.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
9.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals Plot No. 224, Sector 23. Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Orphesic Forte 650/50mg

	Composition	Each Tablet Contains: Orphenadrine citrate…50mg Paracetamol…650mg
	Diary No. Date of R& I & fee	Dy No. 14697: 07-03-2019 (ORIGINAL APPLICATION) Dy No. 26332: 19-09-2022 (DUPLICATE DOSSIER) PKR 20,000/-: 06-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nuberol Forte Tablet by Searle
	GMP status	GMP certificate issued on 02-02-2021 on the basis of inspection conducted on 20-01-2021.
	Remarks of the Evaluator[3].	• The initially applied formulation of the firm was not available in any RRA, the firm vide its letter R&I dated 25-07-2022 has requested to revise their formulation as per RRA approved product along with submission of 30,000-/ fee vide slip number 6187383799 dated 20-07-2022. The newly applied formulation of the firm is as follows: Each Tablet Contains: Orphenadrine citrate…35mg Paracetamol…450mg
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
10.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals Plot No. 224, Sector 23. Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Spasfree plus 10/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Hyoscine Butyl bromide…10mg Paracetamol…500mg
	Diary No. Date of R& I & fee	Dy No. 15190: 07-03-2019 (ORIGINAL APPLICATION) Dy No. 26333: 19-09-2022 (DUPLICATE DOSSIER) PKR 20,000/-: 06-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Buscopan plus tablet by Martin Dow
	GMP status	GMP certificate issued on 02-02-2021 on the basis of inspection conducted on 20-01-2021.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	

Agenda of Evaluator PEC-IX (Mr. Adil Saeed)

11.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMRODOL Tablet 37.5/325 mg
	Composition	Each Film Coated Tablet Contains; Tramadol HCl…… 37.5 mg Paracetamol…… 325 mg
	Dairy No. date of R &I fee	Dy. No. 15360 dated 07.03.2019. Fee paid vide voucher No. 0836409 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics

		ATC Code: N02AJ13
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	2 x 5's
	Approval status of product in Reference Regulatory Authorities	Tramadol Hydrochloride and Paracetamol 37.5 MG/ 325 MG Film-Coated Tablets. MHRA Approved
	Me-too-status	Tonoflex-P Tablet Registration No. 067163 M/s Sami Pharmaceutical (Pvt.) Ltd. SITE Karachi.
	GMP Status	Inspection report dated 18.07.2018 is attached which is older than 3 years.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Latest GMP inspection report shall be submitted as the one provided is older than 3 years. iii. Section approval letter is required.
	Decision: Approved. The Board further directed that registration letter will be issued after submission of: • **Application on the prescribed Form 5 with full fee.** • **Latest GMP inspection report valid within last three years along with the copy of section approval letter.**	
12.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	ACTIV-P Elixir
	Composition	Each 5 ml contains; Paracetamol USP …….. 80mg Pseudoephedrine hydrochloride USP…. 30mg Triprolidine USP……. 1.25mg
	Dairy No. date of R &I fee	Dy. No. 15315 dated 07.03.2019. Fee paid vide voucher No. 0835984 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ATC Code: Not Available for this combination.
	Type of form	Form-5
	Finished product specifications	Product Specifications: Amros
	Pack size and Demand Price	60mL and 90mL. As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities	Could not be verified. The firm has provided reference of Actified P Syrup GSK India.
	Me-too-status	Actifed P Elixir Reg. No. 002681 M/s GSK Ltd. West Warf Karachi.
	GMP Status	Inspection report dated 18.07.2018 is attached which is older than 3 years.
	Remark of the Evaluator.	i. The Form-5 is unsigned. ii. Proposed composition of ACTIV-DM Syrup is given instead of ACTIV-P Elixir. iii. Latest GMP inspection report shall be submitted as the one provided is older than 3 years. iv. Section approval letter is required. v. Evidence of approval of product in RRA is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
13.	Name and address of manufacture / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area Karachi.

		(DML No. 000350) Tablet Section (General)
	Brand Name + Dosage Form and Strength	ACECODONE Immediate Release Tablet 6.12mg/ 325mg
	Composition	Each Immediate Release Tablet Contains; Benzhydrocodone……. 6.12 mg Acetaminophen …… 325 mg
	Dairy No. date of R &I fee	Dy. No. 12250 dated 03.04.2018. Fee Rs. 50,000/- paid vide voucher No. 0613554 dated 09.03.2018, endorsed on 28.03.2018
	Pharmacological Group	Narcotic Analgesic ATC Code: Not Available.
	Type of form	Form-5D
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	14's. As per SRO
	Approval status of product in Reference Regulatory Authorities	APADAZ (benzhydrocodone and acetaminophen) tablets, for oral use Immediate-release tablets: 6.12 mg benzhydrocodone (equivalent to 6.67 mg benzhydrocodone hydrochloride) and 325 mg acetaminophen FDA Approved.
	Me-too-status	The Drug is not available in Pakistan
	GMP Status	Last inspection conducted on 27.02.2020. GMP Status is Good.
	Remark of the Evaluator.	i. The innovator is using Benzhydrocodone HCl salt, the applicant has mentioned the base in proposed master formulation. ii. The product applied is a new drug. Stability Studies are required as per guidelines of 291st meeting of the Registration Board.
	Decision: The Board deferred the case for: • **Confirmation of narcotic section from Licensing Division.** • **Submission of stability data as per the guidelines of 293rd meeting of Registration Board.** • **Revision of formulation from Benzhydrocodone 6.12mg to Benzhydrocodone HCl 6.12mg along with the submission of Rs. 75,000/- for pre-registration variation fee as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.**	
14.	Name and address of manufacture / Applicant	M/s High-Q Pharmaceutical, Plot No. 224/23 Korangi Industrial Area, Karachi. (DML No. 000597) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Loxicam P Tablet 4 mg/ 500 mg
	Composition	Each Tablet Contains; Lornoxicam……. 4 mg Paracetamol (USP) ….. 500 mg
	Dairy No. date of R &I fee	Dy. No. 11027 dated 03.09.2018. Fee Rs. 50,000/- paid vide voucher No. 0539859 dated 03.08.2018, endorsed on 03.09.2018
	Pharmacological Group	Lornoxicam is an NSAID. Paracetamol is an analgesic and antipyretic. ATC Code: Not Available.
	Type of form	Form-5D
	Finished product specifications	High-Q Specifications
	Pack size and Demand Price	10's.
	Approval status of product in Reference Regulatory Authorities	Could not be verified

	Me-too-status	Not available in Pakistan
	GMP Status	Last GMP Inspection was conducted on 15.08.2020. GMP status is good.
	Remark of the Evaluator.	i. Approval status of product in Reference Regulatory Authority is required. ii. The product applied is a new drug. Stability Studies are required as per guidelines of 291st meeting of the Registration Board
	Decision: Deferred for; • **Evidence of approval of applied formulation in reference regulatory authorities/agencie which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status along with registration number, brand name and name of firm.**	
15.	Name and address of manufacture / Applicant	M/s High-Q Pharmaceutical, Plot No. 224/23 Korangi Industrial Area, Karachi. (DML No. 000597) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Loxicam P Tablet 4 mg/ 325 mg
	Composition	Each Tablet Contains; Lornoxicam……. 4 mg Paracetamol (USP) ….. 325 mg
	Dairy No. date of R &I fee	Dy. No. 29493 dated 03.09.2018. Fee Rs. 50,000/- paid vide voucher No. 0590317 dated 03.08.2018, endorsed on 03.09.2018
	Pharmacological Group	Lornoxicam is an NSAID. Paracetamol is an analgesic and antipyretic. ATC Code: Not Available.
	Type of form	Form-5D
	Finished product specifications	High-Q Specifications
	Pack size and Demand Price	14's.
	Approval status of product in Reference Regulatory Authorities	Could not be verified
	Me-too-status	Not available in Pakistan
	GMP Status	Last GMP Inspection was conducted on 15.08.2020. GMP status is good.
	Remark of the Evaluator.	i. The reference provided is of India. Approval status of product in Reference Regulatory Authority is required. ii. The product applied is a new drug. Stability Studies are required as per guidelines of 291st meeting of the Registration Board
	Decision: Deferred for; • **Evidence of approval of applied formulation in reference regulatory authorities/agencie which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status along with registration number, brand name and name of firm.**	
16.	Name and address of manufacture / Applicant	M/s High-Q Pharmaceutical, Plot No. 224/23 Korangi Industrial Area, Karachi. (DML No. 000597) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Loxicam P8 Tablet 8 mg/ 500 mg
	Composition	Each Tablet Contains; Lornoxicam……. 8 mg Paracetamol (USP) ….. 500 mg

	Dairy No. date of R &I fee	Dy. No. 29496 dated 03.09.2018. Fee paid Rs. 50,000/- vide voucher No. 0600171 dated 03.08.2018, endorsed on 03.09.2018
	Pharmacological Group	Loroxicam is an NSAID. Paracetamol is an analgesic and antipyretic. ATC Code: Not Available.
	Type of form	Form-5D
	Finished product specifications	High-Q Specifications
	Pack size and Demand Price	10's.
	Approval status of product in Reference Regulatory Authorities	Could not be verified
	Me-too-status	Not available in Pakistan
	GMP Status	Last GMP Inspection was conducted on 15.08.2020. GMP status is good.
	Remark of the Evaluator.	i. Approval status of product in Reference Regulatory Authority is required. ii. The product applied is a new drug. Stability Studies are required as per guidelines of 291st meeting of the Registration Board.
	Decision: Deferred for; • **Evidence of approval of applied formulation in reference regulatory authorities/agencie which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status along with registration number, brand name and name of firm.**	
17.	Name and address of manufacture / Applicant	M/s High-Q Pharmaceutical, Plot No. 224/23 Korangi Industrial Area, Karachi. (DML No. 000597) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Loxicam P8 Tablet 8 mg/ 325 mg
	Composition	Each Film Coated Tablet Contains; Lornoxicam……. 8 mg Paracetamol (USP) ….. 325 mg
	Dairy No. date of R &I fee	Dy. No. 11028 dated 03.09.2018. Fee paid Rs. 50,000/- vide voucher No. 0583041 dated 03.08.2018, endorsed on 03.09.2018
	Pharmacological Group	Lornoxicam is an NSAID. Paracetamol is an analgesic and antipyretic. ATC Code: Not Available.
	Type of form	Form-5D
	Finished product specifications	High-Q Specifications
	Pack size and Demand Price	10's.
	Approval status of product in Reference Regulatory Authorities	Could not be verified
	Me-too-status	Not available in Pakistan
	GMP Status	Last GMP Inspection was conducted on 15.08.2020. GMP status is good.
	Remark of the Evaluator.	i. Approval status of product in Reference Regulatory Authority is required. ii. The product applied is a new drug. Stability Studies are required as per guidelines of 291st meeting of the Registration Board.
	Decision: Deferred for; • **Evidence of approval of applied formulation in reference regulatory authorities/agencie which were declared/approved by the Registration Board in its 275th meeting.**	

	• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status along with registration number, brand name and name of firm.**	
18.	Name and address of manufacture / Applicant	M/s Barrett Hodgson Pakistan (Pvt) Ltd, F/423, SITE Karachi. (DML No. 000457) Tablet Section (General)
	Brand Name + Dosage Form and Strength	FEBROL ULTRA FAST TABLET 75mg + 650mg
	Composition	Each Tablet Contains; Tramadol HCl …….. 75 mg Paracetamol …… 650 mg
	Dairy No. date of R &I fee	Dy. No. 56715 dated 08.02.2019. Fee paid Rs. 20,000/- vide voucher No. 0817597 dated 31.01.2019, endorsed on 08.02.2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics ATC Code: N02AJ13
	Type of form	Form-5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	10's Rs. 400/- 20's Rs. 800/- 30's Rs 1200/-
	Approval status of product in Reference Regulatory Authorities	Tramadol/Paracetamol 75 mg / 650 mg tablets MHRA approved
	Me-too-status	Tonoflex-P Forte Reg. No. 094798 M/s Sami Pharmaceuticals (Pvt.) Ltd. S.I.T.E. Karachi
	GMP Status	GMP inspecton report provided is dated 28.08.2018, which older than 3 years.
	Remark of the Evaluator.	atest GMP inspection report is required.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in its 293rd meeting.	
19.	Name and address of manufacture / Applicant	M/s MBL Pharma, B-77-A, H.I.T.E. Hub, Pakistan (DML No. 000495) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Panticol tablet, 500mg/ 4mg/ 60mg
	Composition	Each Tablet Contains; Paracetamol BP…… 500 mg Chlorpheniramine Maleate BP …..4 mg Pseudoephidirine HCl BP……..60 mg
	Dairy No. date of R &I fee	Dy. No. 14159 dated 07.03.2019. Fee paid Rs. 20,000/- vide voucher No. 0579778 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	pseudoephedrine, combinations ATC Code: R01BA52
	Type of form	Form-5
	Finished product specifications	MBL Specifications
	Pack size and Demand Price	10x10, Rs. 170/-
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too-status	Panadol CF Tablet Reg. No. 013113 M/s GSK Pakistan Ltd. West Wharf Karachi.
	GMP Status	Inspection report dated 28.02.2019 is provided which is older than 3 years.
	Remark of the Evaluator.	i. Latest GMP inspection report is required. ii. Evidence of Approval status of product in Reference Regulatory Authorities is required.

		iii. Product is applied on MBL Specifications.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
20.	Name and address of manufacture / Applicant	M/s MBL Pharma, B-77-A, H.I.T.E. Hub, Pakistan (DML No. 000495) Tablet Section (General)
	Brand Name + Dosage Form and Strength	PARATRAM Tablets 37.5mg/ 325mg
	Composition	Each Tablet Contains; Tramadol HCl BP…… 37.5 mg Paracetamol BP …….. 325 mg
	Dairy No. date of R &I fee	Dy. No. 14176 dated 07.03.2019. Fee paid Rs. 20,000/- vide voucher No. 0579783 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics ATC Code: N02AJ13
	Type of form	Form-5
	Finished product specifications	MBL Specifications
	Pack size and Demand Price	1x10's. Rs. 107.60/- per pack
	Approval status of product in Reference Regulatory Authorities	rapadex 37.5 mg/325 mg film coated tablets MHRA Approved
	Me-too-status	Tonoflex-P Reg. No. 067163 M/s Sami Pharmaceuticals (Pvt) Ltd SITE Karachi
	GMP Status	Inspection report dated 28.02.2019 is provided which is older than 3 years.
	Remark of the Evaluator.	i. Latest GMP inspection report is required. ii. The product approved in RRA is film coated, whereas applied product is not film coated. This needs to be corrected along with submission of requisite fee.
	Decision: Approved with USP specifications as per following details. • **Registration Board directed the firm to revise the formulation from uncoated to film coated tablet and submission of fee that is Rs. 7,500/- for pre-registration variation fee as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.** • **Submission of latest GMP inspection report valid within last three years.** • **Label claim:** **Each film coated tablet contains:** **Paracetamol……325mg** **Tramadol HCl……37.5mg**	
21.	Name and address of manufacture / Applicant	M/s Fresh Pharmaceutical, Plot No. 7, Street No. S-6, National Industrial Zone Rawat, Islamabad. (DML No. 000827) Tablet Section (General)
	Brand Name + Dosage Form and Strength	F-Dol Tablet 37.5mg/325mg
	Composition	Each film coated tablet contains; ramadol HCl …….. 37.5 mg aracetamol ……. 325 mg
	Dairy No. date of R &I fee	Dy. No. 17074 dated 09.03.2019. Fee paid Rs. 20,000/- vide voucher No. 1901514 dated 07.03.2019, endorsed on 08.02.2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics ATC Code: N02AJ13
	Type of form	Form-5A, Unsigned
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	rapadex 37.5 mg/325 mg film coated tablets MHRA Approved
	Me-too-status	Tonoflex-P Reg. No. 067163 M/s Sami Pharmaceuticals (Pvt) Ltd SITE Karachi
	GMP Status	Last Inspection was conducted on 31.05.2022. GMP Status is Good
	Remark of the Evaluator.	pplication is required to be submitted on Form-5. Correct signed form shall be submitted along with requisite fee.
	Decision: Approved. The Board further directed that registration letter will be issued after submission of application on the prescribed Form 5 with full fee.	
22.	Name and address of manufacture / Applicant	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot No. 44 A-B, Sunder Industrial Estate Lahore. (DML No. 000847) Tablet Section (General)
	Brand Name + Dosage Form and Strength	PARANEXT Cough Suppressant 500/30/15 mg Tablet
	Composition	Each Tablet Contains; Paracetamol …….. 500 mg Pseudoephedrine as HCl …….. 30 mg Dextromethorphan as Hydrobromide……15 mg
	Dairy No. date of R &I fee	Fee paid Rs. 20,000/- vide voucher No. 0827398 dated, endorsed on 07.03.2019 **Duplicate Dossier** Dy. No. 26335 dated 19.09.2022
	Pharmacological Group	Antipyretic + Antitussive ATC Code: Not Available for this formulation.
	Type of form	Form-5
	Finished product specifications	In-House Specifications.
	Pack size and Demand Price	10's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified. Firm has mentioned Panadol Cold & Flu Original Formula Australia, but the reference is not verifiable)
	Me-too-status	Not Available.
	GMP Status	Inspection conducted on 18.02.2022. GMP status good.
	Remark of the Evaluator.	i. Firm has applied for in-house specifications. ii. Approval status of product in Reference Regulatory Authorities could not be confirmed. iii. Me-too of the applied product is not available. The firm has mentioned the same in their application also. The application shall be resubmitted on the relevant Form.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
23.	Name and address of manufacture / Applicant	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot No. 44 A-B, Sunder Industrial Estate Lahore. (DML No. 000847) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Paranext Tension Headache 500/300/45 mg Tablet
	Composition	Each Tablet Contains; Acetaminophen …. 200 mg Aspirin ……..300 mg Caffeine……45 mg
	Dairy No. date of R &I fee	Fee paid Rs. 20,000/- vide voucher No. 0827399, endorsed on 07.03.2019 **Duplicate Dossier** Dy. No. 26338 dated 19.09.2022
	Pharmacological Group	Antipyretic + NSAID OTHER ANALGESICS AND ANTIPYRETICS

		ATC Code: N02BE51
	Type of form	Form-5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	10's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities	nadin Extra Tablets MHRA Approved
	Me-too-status	Could not be confirmed. Firm has mentioned Nopain Tablet Reg. No. 005413 as me-too reference. The formulation of Nopain tablet is; ASPIRIN 300MG, PARACETAMOL 200MG, CAFFEINE 30MG (caffeine in applied formulation is 45 mg),
	GMP Status	Inspection conducted on 18.02.2022. GMP status good.
	Remark of the Evaluator.	i. In name of product, a strength is mentioned as 500 mg, no active ingredient is being used at this strength. Name correction is required. ii. Me-too of the applied product needs clarification as there is difference in quantity/ label claim of caffeine between me-too and applied product.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
24.	Name and address of manufacture / Applicant	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot No. 44 A-B, Sunder Industrial Estate Lahore. (DML No. 000847) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Paranext Feminie Pain 500/25/15 mg Film Coated Tablets
	Composition	Each Film-Coated Tablet Contains; Acetaminiphen ……. 500 mg Pamabrom ……. 25 mg Pyriliamine …….15 mg
	Dairy No. date of R &I fee	Fee paid Rs. 20,000/- vide voucher No. 0827400, endorsed on 07.03.2019 **Duplicate Dossier** Dy. No. Nil dated 19.09.2022
	Pharmacological Group	Antipyretic + diuretic ATC Code:
	Type of form	Form-5
	Finished product specifications	In-House Specifications.
	Pack size and Demand Price	10's, 20's, 100's. As per SRO
	Approval status of product in Reference Regulatory Authorities	ould not be verified.
	Me-too-status	Not Available.
	GMP Status	Inspection conducted on 18.02.2022. GMP status good.
	Remark of the Evaluator.	i. Me-too of the applied product is not available. The firm has mentioned the same in their application also. The application shall be resubmitted on the relevant Form. ii. The Approval status of product in RRA could not be verified.
	Decision: Deferred for; • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

25.	**Name and address of manufacturer / Applicant**	**M/s Hamaz Pharmaceuticals Pvt Ltd .Business City Plaza, Hall # 1, 2nd Floor, Bosan Road, Multan, Pakistan**
	Brand Name + Dosage Form + Strength	T Gesic P Tablet 37.5/325mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl…..…37.5mg Paracetamol……..325mg
	Diary No. Date of R& I & fee	Dy.No 15715 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved.
	Me-too status (with strength and dosage form)	Tramal Plus tablet by M/s Searle Company Ltd, Reg No.77129
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
26.	**Name and address of manufacturer / Applicant**	**M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**
	Brand Name + Dosage Form + Strength	Verat Tablet 450/35mg
	Composition	Each Film Coated Tablet Contains: Paracetamol…….450mg Orphenadrine Citrate…….35mg
	Diary No. Date of R& I & fee	Dy.No 14321 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Skeletal muscle relaxant/ Antipyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Norgesic tablet (uncoated) 35mg/450mg, TGA Approved
	Me-too status (with strength and dosage form)	Nuberol 35/450mg Tablet, Searle Pakistan, Reg. No. 020373.
	GMP status	Last GMP inspection was conducted on 26-02-2018 satisfactory and the report concludes satisfactory level of GMP compliance.
	Remarks of Evaluator: Evidence of approval of applied formulation as "Film coated tablet", in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting shall be submitted or revise the formulation as per innovator product along with submission of revised Form 5 and fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved with innovator's specifications as per following details. • **Registration Board directed the firm to revise the formulation from film coated to uncoated tablet and submission of fee that is Rs. 7,500/- for pre-registration variation fee as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.** • **Submission of latest GMP inspection report valid within last three years.** • **Label claim:** **Each tablet contains:** **Paracetamol…….450mg** **Orphenadrine Citrate…….35mg**	
27.	**Name and address of manufacturer / Applicant**	**M/s Webrose Pharmaceuticals. Plot # 1, Street # 10, National Industrial Zone, Rawat, Pakistan**
	Brand Name + Dosage Form + Strength	Glogesic Forte Tablet
	Composition	Each Tablet Contains: Paracetamol……..…650mg

		Orphenadrine Citrate…….50mg
	Diary No. Date of R& I & fee	Dy.No 15035 dated 07-03-2019
	Pharmacological Group	Skeletal muscle relaxant/ Antipyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Nuberol forte Tablet, Searle Pakistan, Reg. No. 020373.
	GMP status	--
	Remarks of the Evaluator II: • Evidence of approval of applied formulation as "Film coated tablet", in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting shall be submitted. • Submit latest GMP inspection report valid within last three years.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
28.	**Name and address of manufacturer / Applicant**	**M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi**
	Brand Name + Dosage Form + Strength	Ascopan Plus Tablet 10/500mg
	Composition	Each film coated tablet contains: Hyoscine Butyl bromide…….10mg Paracetamol…….500mg
	Diary No. Date of R& I & fee	Dy. No 15298 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antispasmodic/ Antipyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Buscopan Plus Tablets approved by Germany.
	Me-too status (with strength and dosage form)	Spasmed Plus Tablets of M/s Genome, Reg. No. 068384.
	GMP status	Last GMP inspection report dated 18-07-2018, concludes Good level of GMP compliance.
	Remarks of the Evaluator II:	
	Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
29.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
	Brand Name + Dosage Form + Strength	Medidol Plus Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol HCl…..…37.5mg Paracetamol……..325mg
	Diary No. Date of R& I & fee	Dy.No 13462 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form-5
	Finished product Specifications	--
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved.
	Me-too status (with strength and dosage form)	Tramal Plus tablet by M/s Searle Company Ltd, Reg No.77129
	GMP status	GMP inspection report conducted on 14-12-2020 is provided wherein it is concluded that the firm is considered to be operating

		at satisfactory level of compliance with cGMP guidelines as per Drug Act, 1976 and rules framed there under
	Remarks of the Evaluator [II]: Firm has not submitted any reference for drug product specifications, whereas USP monograph is available for applied formulation.	
	Decision: Approved with USP specifications. Registration Board further decided that registration letter will be issued after submission of fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	
30.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Isalamabad**
	Brand Name + Dosage Form + Strength	Davitradol-P Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol HCl.…..…37.5mg Paracetamol……..325mg
	Diary No. Date of R& I & fee	Dy.No 15821 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved.
	Me-too status (with strength and dosage form)	Tramal Plus tablet by M/s Searle Company Ltd, Reg No.77129
	GMP status	The firm is granted GMP certificate based on inspection conducted 02-02-2022.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
31.	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Windol Tablet 500/65/2mg
	Composition	Each Tablet Contains: Paracetamol……500mg Caffeine…..…65mg Chlorpheniramine…..…2mg
	Diary No. Date of R& I & fee	Dy.No 17290 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	N/A
	GMP status	GMP certificate issued on 15-07-2019 on the basis of inspection conducted on 07-03-2019.
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for following points: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
32.	**Name and address of manufacturer / Applicant**	**M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan**

	Brand Name + Dosage Form + Strength	Obroxon Capsule 250mg/300mg
	Composition	Each Capsule Contains: Chlorzoxazone……250mg Paracetamol……300mg
	Diary No. Date of R& I & fee	Dy.No 16084 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antipyretic/Muscel relaxant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specfications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	N/A
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator II: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
33.	**Name and address of manufacturer / Applicant**	**M/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name + Dosage Form + Strength	Cetor Forte Tablet 50mg
	Composition	Each Tablet Contains: Paracetamol…….650mg Orphenadrine Citrate…….50mg
	Diary No. Date of R& I & fee	Dy.No 15035 dated 07-03-2019
	Pharmacological Group	Skeletal muscle relaxant/ Antipyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Nuberol forte Tablet, Searle Pakistan, Reg. No. 020373.
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator II: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
34.	**Name and address of manufacturer / Applicant**	**M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh**
	Brand Name + Dosage Form + Strength	Tramin 325/37.5 mg Tablet
	Composition	Each film coated tablet contains: Paracetamol……325mg Tramadol……..37.5mg
	Diary No. Date of R& I & fee	Dy.No 16275 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antipyretic/Analgesic

	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved.
	Me-too status (with strength and dosage form)	Tramal Plus tablet by M/s Searle Company Ltd, Reg No.77129
	GMP status	Panel Inspection for grant of DML dated 11-04-18 recommended grant of DML by the way of formulation for Tablet(general), Capsule(general) & Liquid syrup (general) Sections.
	Remarks of the Evaluator [II]:	
	Decision: Approved. The Board decided that registration letter will be issued after submission of latest GMP inspection report valid within last three years.	

Agenda of Evaluator PEC-XVII

35.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	RAMAPOL TABLET
	Composition	Each film-coated tablet contains: - Tramadol hydrochloride…...37.5mg Paracetamol…….325mg
	Diary No. Date of R & I & fee	Dy. No.1125 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577582 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Centrally acting analgesic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ultracet coated tablet (Janssen Pharma) US FDA approved. In MHRA both coated and uncoated available.
	Me-too status	Tramal plus film coated tablet of M/s The Searle Company, Lahore. Registration No. 077129
	GMP status	**Not provided**
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise master formulation/composition and manufacturing outlines as per label claim (film-coated tablet) since the composition provided is for chewable tablet. • Revise finished drug product specifications as per official monograph (USP). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. • **Registration Board directed the firm to revise the formulation from chewable tablet to film coated tablet and submission of fee that is Rs. 30,000/- for revision of formulation from chewable tablet to film coated Tablet and revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021 along with the relevant documents.** • **Verification of fee challan submitted with initial application as per decision of 285th meeting of Registration Board.** • **Submission of latest GMP inspection report valid within last three years.** • **Label claim:** **Each film coated tablet contains:** **Paracetamol……325mg** **Tramadol HCl……37.5mg**	

36.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	ORPH PLUS TABLET
	Composition	Each film-coated tablet contains: - Orphenadrine citrate…...35mg Paracetamol…….450mg
	Diary No. Date of R & I & fee	Dy. No.1132 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577583 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Central anticholinergic/analgesic/muscle relaxant
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's × 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Norgesic tablet (uncoated) 35mg/450mg, TGA Approved
	Me-too status	Maggesic 450/35mg Tablet of M/s Magns Pharmaceuticals, Faisalabad. Registration No. 103383
	GMP status	**Not provided**
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise label claim as per reference product as: Each uncoated tablet contains: Orphenadrine citrate….35mg Paracetamol…….450mg • Firm has claimed manufacturer specifications, while official monograph not available. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovator's specifications. • **Registration Board directed the firm to revise the formulation from film coated to uncoated tablet and submission of fee that is Rs. 7,500/- for pre-registration variation fee as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.** • **Verification of fee challan submitted with initial application as per decision of 285th meeting of Registration Board.** • **Submission of latest GMP inspection report valid within last three years.** • **Label claim:** **Each tablet contains:** **Orphenadrine citrate….35mg** **Paracetamol…….450mg**	
37.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	PERKOSET tablet
	Composition	Each tablet contains: Oxycodone (As hydrochloride) ….....10mg Paracetamol……650mg
	Diary No. Date of R & I & fee	Dy. No. 1249 dated 11-01-2011, Rs. 8,000/- challan dated 14-12-2010 (Photocopy), Dy. No. 25868 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955344 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Opioid analgesic
	Type of Form	Form 5
	Finished product Specification	USP specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) Percocet (Oxycodone HCl 10 mg, Acetaminophen 325 mg) of Endo pharmaceuticals.
	Me-too status	**Couldn't be confirmed**
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (Psychotropic) section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Revise label claim as per reference product as: Each tablet contains: Oxycodone hydrochloride….10mg Acetaminophen……325mg • Provide evidence of drug with same formulation/composition as approved by DRAP (Me-too/generic) with proprietary name, registration number and manufacturer or else submit application on Form 5D and stability study data as per guidelines of 293rd meeting of Registration Board along with submission of applicable fee. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Firm has provided undertaken that the product (Perkoset tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: The Board deferred the case for submission of following points: • **stability data as per the guidelines provided in 293rd meeting of Registration Board.** • **Confirmation of narcotics-psychotropic section.**	
38.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	PERKOSET Syrup
	Composition	Each 5ml contains: Oxycodone (As hydrochloride) ….....5mg Paracetamol……325mg
	Diary No. Date of R & I & fee	Dy. No. 1250 dated 11-01-2011, Rs. 8,000/- challan dated 14-12-2010 (Photocopy), Dy. No. 25867 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955343 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Opioid analgesic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	**Could not be confirmed**
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Oral liquid/syrup section (Psychotropic) available as per panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Revise Each 5ml contains: Oxycodone hydrochloride ….....5mg Paracetamol……325mg

		• Provide evidence of drug with same formulation/composition as approved by DRAP (Me-too/generic) with proprietary name, registration number and manufacturer or else submit application on Form 5D and stability study data as per guidelines of 293rd meeting of Registration Board along with submission of applicable fee. • The product is non-pharmacopoeial. • Firm has provided undertaken that the product (Perkoset syrup) has never been discussed or deferred in any meeting and that given information are true. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: The Board deferred the case for submission of following points: • **stability data as per the guidelines provided in 293rd meeting of Registration Board.** • **Confirmation of narcotics-psychotropic section.**	
39.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	PARACETAMOL 120mg/5ml Suspension
	Composition	Each 5ml suspension contains: Paracetamol…….120mg
	Diary No. Date of R & I & fee	Dy. No. 340 dated 25-05-2011, Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539226 (Photocopy). (Duplicate Dossier, R & I verified)
	Pharmacological Group	Non-narcotic analgesic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	60ml,450ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	Paracetamol 120 mg/5 ml Oral Suspension by M/s Pinewood Laboratories Limited (MHRA approved)
	Me-too status	Fempol 120mg/5ml suspension by M/s Atlantic Pharmaceuticals, Peshawar. (Reg# 062314)
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• **Provide DRAP R & I cover letter copy for differential fee submission in the year 2016.** • Form-5 is not signed by the firm's management. • Provide evidence of approval of relevant section by Licensing Division, DRAP Islamabad. • Provide most recent GMP inspection report conducted within last 03 years. • Revise pharmacological group as "anilides". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. • **Verification of all the fee challans as per decision of 285th meeting of Registration Board since photo copies of the challans are submitted.** • **Moreover, the Board decided that registration letter will be issued after submission of latest GMP inspection report valid within last three years.**	
40.	Name and address of manufacturer/ Applicant	M/s Tagma Pharma (Pvt) Ltd. 12.5Km, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	CO-CODAMOL tablet
	Composition	Each tablet contains: Paracetamol…...500mg Codeine phosphate…..15mg

	Diary No. Date of R & I & fee	Dy. No. dated, Rs. 8,000/- dated -04-2011 (Fee Challan copy provided) Dy. No.32397 dated 31-01-2020 Differential fee Rs. 12,000/- dated 30-01-2020 vide challan No.1953743 dated 29-01-2020. (original) (Duplicate dossier)
	Pharmacological Group	Opiate/analgesic/antipyretic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved, uncoated tablet) Co-codamol 15mg/500mg tablets, Each Co-codamol 15mg/500mg tablet contains paracetamol 500mg, codeine phosphate hemihydrate 15mg.
	Me-too status	Rakadine Tabletof M/s Rakaphoshi Pharmaceuticals, Peshawar. Registration No. 092822
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide DRAP R & I stamped cover letter copy of **initial submission** of registration application in April, 2011. • Tablet (Psychotropic/narcotic) Section approved vide letter No.F.1-8/94-Lic (Vol-III) dated 14-06-2018. • Revise label claim as per reference product as: Each tablet contains: Paracetamol……500mg Codeine phosphate hemihydrate……15mg • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Registration Board deferred the case for verification of R&I number of initially submitted application.	
41.	Name and address of manufacturer/ Applicant	M/s Convell Laboratories, Saidu Sharif, Swat.
	Brand Name + Dosage Form + Strength	Convidol tablet
	Composition	Each tablet contains: - Paracetamol…….500mg Caffeine…….65mg Chlorpheniramine maleate…….2mg
	Diary No. Date of R & I & fee	Dy. No.12 dated 14-02-2011, Rs. 8,000/- dated 14-02-2011 (Fee challan copy provided) Dy.No. dated 27-2-2017, Differential fee Rs. 12,000/- dated 27-02-2017 vide challan No.0603329 dated 27-02-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Analgesic, antipyretic & anti-histamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	**Could not be confirmed**
	Me-too status	Hesmol Extra tablets of Wisodm pharmaceuticals, Peshawar. Registration No. 078571
	GMP status	**Not provided**
	Remarks of the Evaluator (PEC-XVII)	• Overages have been mentioned in master formulation. Provide justification for the added overages or else revise master formulation. • Provide list of machinery to be utilized in manufacturing of applied product/formulation.

		• Provide evidence of approval of applied formulation in reference regulatory authorities as approve by the Registration Board in its 275th meeting. • Provide most recent/last GMP compliance inspection report. • Drug manufacturing license validity status need to be verified from Licensing Division. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following points: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Confirmation of current status of Drug Manufacturing License of the firm whether valid or otherwise.** • **Overages have been mentioned in master formulation. Provide justification for the added overages or else revise master formulation.** • **Provide list of machinery to be utilized in manufacturing of applied product/formulation.** • **Provide evidence of relevant section approval by Licensing division, DRAP Islamabad.**	
42.	Name and address of manufacturer/ Applicant	M/s English Pharmaceutical Industries, Link Kattar Bund road, Thokar Niaz Baig, Multan road, Lahore.
	Brand Name + Dosage Form + Strength	CAMRI-P TABLET
	Composition	Each tablet contains: - Lornoxicam……8mg Paracetamol…….500mg
	Diary No. Date of R & I & fee	Dy. No.5197 dated 12-06-2012, Rs. 8,000/- dated 12-06-2012 (Fee challan copy dated 08-06-2012 provided) Dy.No. dated, Differential fee Rs. /- dated vide challan No. dated. "Duplicate dossier, R & I verified"
	Pharmacological Group	Non-narcotic & analgesic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide DRAP R & I stamped cover letter copy of differential fee submission and differential fee challan copy. • Method of analysis provided is for tramadol HCl and Acetaminophen, while title given is of Tenofovir disoproxil fumarate. Please clarify and revise. • Provide evidence of approval of applied formulation in reference regulatory authorities as approve by the Registration Baord in its 275th meeting. • Provide evidence of drug already approved by DRAP (generic/me-too) with brand name, registration number and manufacturer. • Provide most recent/last GMP compliance inspection report. • Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	

	• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of submission of differential fee.** • **Method of analysis provided is for tramadol HCl and Acetaminophen, while title given is of Tenofovir disoproxil fumarate. Please clarify and revise.** • **Provide evidence of relevant section approval by Licensing division, DRAP Islamabad.**

Agenda of Evaluator PEC-XV

43.	Name and address of manufacturer / Applicant	M/s. WnsFeild Pharmaceuticals, Plot No. 122, Block A, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form+ Strength	Newbral tablets (450+35 mg)
	Diary No. Date of R& I & fee	(Original Dossier) Dy. No. 100 dated 16-04-2012 Rs. 8,000/- (Original) dated 06-03-2012 Differential fee (Original) Rs.12,000/- submitted on 14-10-2015
	Composition	Each tablet contains: Paracetamol.....450mg Orphenadrine Citrate.....35mg
	Pharmacological Group	Analgesic and antipyretic combination
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack Size & Demanded Price	100's/ As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Norgesic tablet (uncoated) 35mg/450mg TGA Approved
	Me-too Status	Nuberol 35/450mg Tablet by M/s Searle Pakistan (Reg. # 020373)
	GMP Status	10-12-2020 Conclusion: "As per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and calibration record evaluation, the panel unanimously recommends the grant of cGMP certificate to the firm."
	Remarks of the Evaluator.	▪ 5% overage is mentioned in master formula, revised master formula is required. ▪ Official monograph of applied formulation is not available in available pharmacopoeias (USP, BP, IP, JP) ▪ Tablet (general) section confirmed vide Panel cGMP compliance inspection report dated 10-12-2020.
	Decision of 308th meeting of Registration Board	**Deferred for scientific justification for addition of 5% excess (overage).**
	Response of the Firm	Firm submitted the revised formulation with no overage, requisition submitted without fee.
	Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	

5 <u>Cases of applications submitted on Form 5-F</u>

Agenda of Evaluator PEC-III

44.	Name, address of Applicant / Marketing Authorization Holder	M/s World Biz Pharmaceutical Company, Plot No. 340, Multan Industrial Estate, Multan.
	Name, address of Manufacturing site.	M/s World Biz Pharmaceutical Company, Plot No. 340, Multan Industrial Estate, Multan.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of DML number 000942 issued on 13-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 specifying Oral liquid syrup section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22536: 10-08-2022
	Details of fee submitted	PKR 30,000/-: 09-06-2022
	The proposed proprietary name / brand name	**Para Biz Suspension 120mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Paracetamol ……120mg
	Pharmaceutical form of applied drug	Oral suspension
	Pharmacotherapeutic Group of (API)	Analgesic / antipyretic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Junior Paracetamol Suspension (**MHRA** Approved)
	For generic drugs (me-too status)	Calpol suspension of M/s GSK Pakistan (Reg # 000354)
	Name and address of API manufacturer.	M/s Zenith Chemical Industries (Pvt) Limited. 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore - Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time

		stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in BP for their product against the reference product i.e. PANADOL suspension of GSK Pakistan (Pvt) Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zenith Chemical Industries (Pvt) Limited. 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore - Pakistan		
API Lot No.	ZPAR20-350		
Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-AS-001	RD-AS-002	RD-AS-003
Batch Size	2000 Bottle	2000 Bottle	2000 Bottle
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	15-11-2021	15-11-2021	15-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Zenith Chemical Industries is issued by DRAP on 22-05-2019. The certificate is issued based on the inspection dated 06-12-2018.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with UV spectra, raw data sheets, COA and summary data sheets.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC systems are not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Provide verification studies of drug substance from drug product manufacturer.
- Specifications are mentioned as BP in some sections and USP in other sections.
- Assay method is based on HPLC while verification studies are conducted on UV method.
- Analytical method specifies HPLC method, while assay testing in stability studies is conducted on UV
- Provide copy of commercial invoice for evidence of purchase of the drug substance.

Decision of 320th meeting of Registration Board:

Deferred for;

- Submission of data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submission of verification studies of drug substance from drug product manufacturer.
- Clarification since specifications are mentioned as BP in some sections and USP in other sections.
- Clarification regarding the assay method which is based on HPLC while verification studies are conducted on UV method.
- Clarification since analytical method specifies HPLC method, while assay testing in stability studies is conducted on UV
- Submission of copy of commercial invoice for evidence of purchase of the drug substance.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submission of data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copy of specifications of the drug substance from drug product manufacturer as well.
2.	Submission of verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
3.	Clarification since specifications are mentioned as BP in some sections and USP in other sections.	Applied product is of BP specifications.
4.	Clarification regarding the assay method which is based on HPLC while verification studies are conducted on UV method.	We have adopted alternate method in which assay is based on UV method for stability of batches for CTD purpose. After registration we will adopt pharmacopoeia method and will verify it as per ICH guidelines.
5.	Clarification since analytical method specifies HPLC method, while assay testing in stability studies is conducted on UV	We have adopted alternate method in which assay is based on UV method for stability of batches for CTD purpose. After registration as per undertaking we will adopt pharmacopoeial method for process validation and both accelerated and long term stability studies of commercial batches.

6.	Submission of copy of commercial invoice for evidence of purchase of the drug substance.	Firm has submitted copy of commercial invoice dated 29-10-2021 specifying purchase of 10Kg paracetamol.

Decision: The Board discussed that the official monograph of the applied product is present in B.P whereas the firm has performed the testing according to In-House specifications. The Board decided to defer the case for submission of testing of the applied product according the monograph available in B.P along with the analytical method verification studies for the drug product on the next month time point of long term stability studies for all the 03 stability batches.

45.	Name, address of Applicant / Marketing Authorization Holder	M/s Magns Pharmaceutical. Plot No. 7B, Value Addition City, Sahianwala Road, Khurrianwala, Faisalabad.
	Name, address of Manufacturing site.	M/s Magns Pharmaceutical. Plot No. 7B, Value Addition City, Sahianwala Road, Khurrianwala, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 22-03-2019 issued on the basis of inspection dated 01-03-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manuacturing License (DML) dated 25-11-2016 specifying Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11697: 14-05-2022
	Details of fee submitted	PKR 30,000/-: 15-02-2022
	The proposed proprietary name / brand name	**CETAMOL 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol ……500mg
	Pharmaceutical form of applied drug	white color round uncoated tablet
	Pharmacotherapeutic Group of (API)	Analgesic / antipyretic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol IPCA 500mg Tablet by IPCA Laboratories (**MHRA** Approved)
	For generic drugs (me-too status)	Panadol Tablet of M/s GSK Pakistan (Reg # 000817)
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in BP for their product against the reference product i.e. CALPOL tablet of GSK. Firm has submitted results of CDP in three dissolution medium for their product against the reference product i.e. CALPOL tablet of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510911/017/2020		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-006	T-007	T-008
Batch Size	5000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	02-2021	02-2021	02-2021

Date of Initiation	12-02-2021	12-02-2021	18-02-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Provide verification studies of drug substance from drug product manufacturer.
- Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product.
- Justify why qualitative composition is different from the reference product.
- Provide reference of previous approval of applications with stability study data of the firm (if any)
- Provide evidence of approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Provide copy of commercial invoice for evidence of purchase of the drug substance.
- Provide record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision of 320th meeting of Registration Board:

Deferred for the following;

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Provide verification studies of drug substance from drug product manufacturer.
- Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product.
- Justify why qualitative composition is different from the reference product.
- Provide reference of previous approval of applications with stability study data of the firm (if any)
- Provide evidence of approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Provide copy of commercial invoice for evidence of purchase of the drug substance.
- Provide record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submission of data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copy of specifications of the drug substance from drug product manufacturer as well.
2.	Submission of verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
3.	Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product.	Firm has submitted COA of API batch number 00510911/017/2020 from Pharmagen Ltd.
4.	Justify why qualitative composition is different from the reference product.	Qualitative composition is different from reference product because this is not innovator specifications but all parameters like assay, dissolution, disintegration etc are same and within specified limit as per BP.
5.	Provide reference of previous approval of applications with stability study data of the firm (if any)	No previous PSI inspection of the firm has been conducted
6.	Provide evidence of approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued dated 02-09-2020 based on the inspection dated 22-06-2020.
7.	Provide copy of commercial invoice for evidence of purchase of the drug substance.	Firm has submitted copy of commercial invoice dated 29-07-2020 specifying purchase of 40 Kg paracetamol from Pharmagen.
8.	Provide record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for accelerated and real time stability chambers.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Furthermore, the Board decided that the firm shall submit compatibility studies of excipients with the drug substance since the qualitative composition of the applied product is different from the reference product.**

46.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of the firm issued dated 11-08-2020 based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of regularization of existing facility under DML number 000072 of M/s Sami Pharma which specifies Tablet (General / General antibiotic) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4785: 21-02-2022
	Details of fee submitted	PKR 75,000/-: 17-02-2022
	The proposed proprietary name / brand name	**PROVAS ACTIFAST 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol ……500mg
	Pharmaceutical form of applied drug	white to off white uncoated tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP
	Proposed Pack size	10's, 20's, 30's, 50's and 100's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Panadol ActiFast 500mg Tablet by GlaxoSmithKline Consumer Healthcare (**MHRA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Hebei Jiheng (Group) Pharmaceutical Co. Ltd. Shenzhou Plant Southeast Xijingming Village Donganzhuang Township, Shenzhou County Henshui City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product i.e. PANADOL Actifast tablet of GSK Ireland. Firm has submitted results of CDP in three dissolution medium for their product against the reference product i.e. PANADOL Actifast tablet of GSK Ireland.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Jiheng (Group) Pharmaceutical Co. Ltd. Shenzhou Plant Southeast Xijingming Village Donganzhuang Township, Shenzhou County Henshui City, Hebei Province, China.		
API Lot No.	31709016		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	21-12-2020	21-12-2020	21-12-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of last onsite panel inspection for instant dosage form conducted during last two years i.e. EMPOLI (Empagliflozin) 10mg & 25mg Tablets which was presented in 290th meeting of the registration board & hence approved & registered by registration board Date of inspection: 13th June 2019. The inspection report confirms following points • The HPLC software is 21CFR Compliant. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HE20180054 issued by China Food And Drug Administration valid till 08/07/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (Invoice# 1708ZP03 dated 19th October 2017 with received quantity i.e. 5000 kgs) for the purchase of Paracetamol from M/s Hebei Jiheng

		Shenzhou Pharmaceutical Co., Ltd. China with attestation of DRAP dated 01-11-2017
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete analytical record of product testing of all batches.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Qualitative composition is different from the reference product, since reference product has not used potassium sorbate and pregelatinized starch.
- Justify the use of preservative i.e. potassium sorbate in the applied formulation as tablet.
- Dissolution acceptance in USP is NLT 80% in 30 minutes while the firm has set acceptance criteria NLT 80% in 10 minutes.
- Disintegration test acceptance criteria is NMT 30 minutes, while dissolution criteria is NLT 80% in 10 minutes.

Decision of 320th meeting of Registration Board:

Deferred for the following;

- Qualitative composition is different from the reference product, since reference product has not used potassium sorbate and pregelatinized starch.
- Justify the use of preservative i.e. potassium sorbate in the applied formulation as tablet.
- Dissolution acceptance in USP is NLT 80% in 30 minutes while the firm has set acceptance criteria NLT 80% in 10 minutes.
- Disintegration test acceptance criteria is NMT 30 minutes, while dissolution criteria is NLT 80% in 10 minutes.

Response by the firm:

Firm vide its letter dated 13-09-2022 has submitted a request as follows:
Kindly note that we applied the dossier initially with the brand name of PROVAS ACTIFAST which was later on changed to PROVAS FASTIV vide our letter dated 03-05-2022.

Sr. No	Reason for deferment	Response by the firm
1.	Qualitative composition is different from the reference product, since reference product has not used potassium sorbate and pregelatinized starch.	We have used potassium sorbate and pregelatinized starch same as of innovator formulation. Firm has also submitted PIL of Panadol Actifast Tablets manufactured by GSK Ireland. However we have already submitted API-Excipient compatibility in our dossier for difference in other excipients, API –Excipient compatibility studies attached
2.	Justify the use of preservative i.e. potassium sorbate in the applied formulation as tablet.	We have used potassium sorbate in our formulation same as of innovator formulation
3.	Dissolution acceptance in USP is NLT 80% in 30 minutes while the firm has set acceptance criteria NLT 80% in 10 minutes.	With reference to our letter dated 22nd August 2022 is attached, we have revised our specifications from USP to Innovator's. Our specifications confirms to the Innovator's (GSK) specifications which are more stringent than USP specifications. Revised specifications and testing method (SPTM) and Pharmaceutical Equivalence is provided by the firm
4.	Disintegration test acceptance criteria is NMT 30 minutes, while dissolution criteria is NLT 80% in 10 minutes.	We set the disintegration specification according to USP general monograph for Disintegration <701> which specifies NMT 30 minutes for film coated tablets. Our product is fast dissolving with a dissolution specs of NLT 80% (Q) in 10 minutes and

		disintegration time of our product is also found within 01 minute which correlates with dissolution. We have revised the specification of DT from NMT 30 minutes to NMT 10 minutes. Revised specifications and testing method (SPTM) is provided by the firm.

Decision: Registration Board discussed that the applicant already has the registration of formulation containing Paracetamol 500mg as immediate release tablet whereas the firm has applied for the same formulation having different excipients and there is no change in strength, dosage form, salt form, drug delivery system etc. Considering the fact that different excipients are used in the applied product and already approved formulation, the Board deferred the case for clarification from applicant and then further deliberation.

Agenda of Evaluator PEC-XI

47.	Name, address of Applicant / Marketing Authorization Holder	M/s Bosch Pharmaceuticals (Pvt.) Ltd., Plot No. 209, Sector 23, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Bosch Pharmaceuticals (Pvt.) Ltd., Plot No. 209, Sector 23, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12642 dated 24/05/2022
	Details of fee submitted	PKR 50,000/-: dated 26/04/2021 PKR 25000/- dated 14/03/2022 (Slip#446590164659)
	The proposed proprietary name / brand name	Bofalgan Plus 1gm / 300mg infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Paracetamol……..……..1000mg. Ibuprofen (as sodium dihydrate)…….300mg
	Pharmaceutical form of applied drug	Infusion
	Pharmacotherapeutic Group of (API)	Other Analgesics and Antipyretics
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per S.R.O
	The status in reference regulatory authorities	MAXIGESIC IV paracetamol 1000mg and ibuprofen (as sodium dihydrate) 300mg in 100mL solution for infusion vial TGA Approved
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	GMP certificate issued to the firm on 17-07-2020 based on inspection conducted on 26-06-2019.
	Name and address of API manufacturer.	**Paracetamol:** Mallinckrodt Inc. Raleigh Pharmaceutical Plant 8801 Capital Boulevard Raleigh, North Carolina 27616 **Ibuprofen:** **Manufacturing Facility I:** Solara Active Pharma Sciences Limited., Mathur Road, periyakalapet Puducherry 605014, India

		Manufacturing Facility II: Solara Active Pharma Sciences Limited., AI/B, SIPCOT Industrial Complex, Kudikadu Village, Cuddalore 607005 Tamil Nadu India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Paracetamol:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months of following batches: Batches; 6088907C189, 0057907C398, 4814907C222 The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for following batches; 005712B026 for 02 years, 7637511C029 for 03years, 554210C126 for 04 years. **Ibuprofen:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. ***The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 18months at manufacturing facility I;*** Batches; 3ISH180001, 3ISH180002, 3ISH180003 Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. ***The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 09months at manufacturing facility II;*** Batches; CIBD19001V, CIBD19002V, CIBD19003V,
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that ***is Maxigesic IV Solution for Infusion by M/s AFT Pharmaceuticals New Zealand*** by

		performing quality tests (description, filled volume, particulate matter, Assay).		
	Analytical method validation/verification of product	Firm have submitted analytical method validation studies including accuracy, precision, specificity, linearity and robustness.		
STABILITY STUDY DATA				
Manufacturer of API		**Paracetamol:** Mallinckrodt Inc. Raleigh Pharmaceutical Plant 8801 Capital Boulevard Raleigh, North Carolina 27616 **Ibuprofen:** **Manufacturing Facility I:** Solara Active Pharma Sciences Limited., Mathur Road, periyakalapet Puducherry 605014, India **Manufacturing Facility II:** Solara Active Pharma Sciences Limited., AI/B, SIPCOT Industrial Complex, Kudikadu Village, Cuddalore 607005 Tamil Nadu India		
API Lot No.		Paracetamol; 784520M020 Ibuprofen (as Sodium dihydrate); CISH210013		
Description of Pack (Container closure system)		Clear Transparent glass vial (100ml) with rubber stopper and dark blue aluminum seal with Bosch logo		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		TR-BFP-02	TR-BFP-03	TR-BFP-04
Batch Size		250 Vials	250 Vials	250 Vials
Manufacturing Date		07-2021	07-2021	07-2021
Date of Initiation		07-2021	07-2021	07-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	No details of previous inspection submitted the firm		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of CoPP certificate #01-0028-2016-02-ES dated 28/01/2016 of M/s Mallinckrodt Inc. Raleigh Pharmaceutical Plant 8801 Capital Boulevard Raleigh, North Carolina 27616 for Acetaminophen USP / Paracetamol Fine Powder issued by USFDA indicating the GMP compliant status of the manufacturer. The firm have submitted copy of GMP certificate #WC-0126 dated 26/07/2019 of M/s Solara Active Pharma Sciences Limited., R.S.No. 33& 34, Mathur Road, periyakalapet, Puducherry-605014, India ***(for Ibuprofen Sodium Dihydrate)*** issued by Central Drugs Standard Control Organization Ministry of Health and Family welfare India valid upto three years from date of issue. ***This certificate is being issued subject to condition that the firm shall obtain NOC from competent authority, case to case basis, to manufacturer the above mentioned active substance for purpose of export only, as above***		

		mentioned active substance are not approved for manufacturer for sale in India
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 19075278 dated 17/02/2021 in the name of M/s Bosch Pharmaceuticals (Pvt.) Ltd., for import of 1500Kg Paracetamol Fine powder (Batch No 784520M020) from M/s Mallinckrodt Chemical Limited attested by AD (I&E) DRAP Karachi on 22/02/2021. Firm has submitted copy of commercial invoice No. 1107300837 dated 16/04/2021 in the name of M/s Bosch Pharmaceuticals (Pvt.) Ltd., for import of 05Kg Ibuprofen Sodium (Batch No CISH210013) from M/s Solara Active Pharma Sciences Limited manufacturing site II attested by AD (I&E) DRAP Karachi on 29/04/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets is submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Submit original fee deposit slip of PKR 25000/-	
1.3.5	• Submit GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years	
1.6.5	• Mention Name and address of API manufacturer (Both paracetamol and Ibuprofen) in this section • Submit Valid GMP certificate / DML of the Drug Substance manufacturer (for ibuprofen) issued by relevant regulatory authority of country of origin. • GMP certificate of manufacturing site I is submitted while API is imported from manufacturing site II	
3.2.S.4	• Copies of specifications and analytical procedure used for routine testing of drug substance paracetamol by drug product manufacturer is required • Analytical method verification studies for paracetamol drug substance by drug product manufacturer is required • Submit Certificate of Analysis (CoA) of the relevant batch used during product development and stability studies from Drug Substance manufacturer. • Copies of specifications and analytical procedure used for routine testing of drug substance Ibuprofen by drug product manufacturer is required • Analytical method validation studies for ibuprofen drug substance by drug product manufacturer is required • Some analytical procedure for ibuprofen drug substance given by drug substace manufacturer is from M/s Shasun chemicals and drugs, clarify? • Submit Certificate of Analysis (CoA) of the relevant batch used during product development and stability studies from Drug Substance manufacturer.	

3.2.S.6	• Reference standard of Ibuprofen drug substance if provided from M/s Shasun chemicals and drugs while Solara Active Pharma Sciences Limited is manufacturer of Ibuprofen, clarify?	
3.2.S.7	• Stability data of paracetamol of different batches at real time and accelerated conditions is submitted clarify?	
3.2.P.1	• Justification is required for not preforming pH test and sterility test in pharmaceutical equivalence as per submitted specification of drug product	
3.2.P.6	• Reference standard of Ibuprofen drug substance if provided from M/s Shasun chemicals and drugs while Solara Active Pharma Sciences Limited is manufacturer of Ibuprofen, clarify?	
3.2.P.8	• Submit 6th month stability study data at both real time and accelerated conditions • Initial page of stability summary sheet containing batch No. of FPP, API, storage conditions, date of manufacturing, date of initiation of stability study is not submitted • Stability data of different batches at real time conditions (TR-BFP-02, TR-BFP-03, TR-BFP-04) and Accelerated conditions (TR-BOINJ-02, TR-BOINJ-04, TR-BOINJ-03) is submitted clarify • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
	•	

Decision: The Board deferred the case for clarification of the above mentioned points.

Agenda of Evaluator PEC-VI (Mr. Ishtiaq)

48.	Name, address of Applicant / Marketing Authorization Holder	**M/s HONIG Pharmaceuticals, 14 k.m. Adyala road, Rawalpindi.**
	Name, address of Manufacturing site.	**M/s HONIG Pharmaceuticals, 14 k.m. Adyala road, Rawalpindi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13054 dated 28-05-2022
	Details of fee submitted	PKR 20,000/-: dated 30-03-2022
	The proposed proprietary name / brand name	Relief plus tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol…….. 450 mg Orphenadrine citrate ……..35 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Muscle relaxant/Antipyretic
	Reference to Finished product specifications	Manufacturer specifications.
	Proposed Pack size	10X10 s

	Proposed unit price	As per DPC.
	The status in reference regulatory authorities	NORGESIC Tablet(Paracetamol 450 mg and Orphenadrine 35 mg)un-coated tablet, TGA approved.
	For generic drugs (me-too status)	Duragesic Tablet (Paracetamol 450 mg and Orphenadrine 35 mg), Tabros Pharmaceuticals
	GMP status of the Finished product manufacturer	GMP certificate missing
	Evidence of section approval.	Missing. Firm has provided revised Layout plan approval , dated 18-01-2021
	Name and address of API manufacturer.	**Drug substance Paracetamol USP** **Manufacturing site:** Saakh Pharma (Pvt.) Ltd, Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan. **Drug substance Orphenadrine citrate BP** **Manufacturing site:** R L Fine Chem Pvt. Ltd, Plot no. IP-27-29, KIADB Industrial area, 1st Phase , Kudumalakunte village, Gowribidanur -Taluk, Chikkaballapur Dist, Karnataka- 5612018, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification(missing), batch analysis(missing) and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	**Drug substance Paracetamol USP** **Stability study conditions:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months data missing. Batch No. 18GN60001, 18GN60002 & 18GN60003. **Drug substance Orphenadrine citrate** **Stability study conditions:** Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months data missing. Batch No. 002R7D/ORC, 003R7D/ORC &004R7D/ORC
	Module-III (Drug Product):	The firm has submitted detail of description & composition of the drug product, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies(missing), batch analysis(missing) and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been Performed against Nuberol forte, which is different in composition than applied product. Firm has performed Comparative dissolution profile with product Nuberol forte, which is different in composition than applied product.
	Analytical method validation/verification of product	Method Validation studies have not been performed

STABILITY STUDY DATA			
Manufacturer of API	Drug substance Paracetamol USP Manufacturing site: Saakh Pharma (Pvt.) Ltd, Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan. Drug substance Orphenadrine citrate BP Manufacturing site: R L Fine Chem Pvt. Ltd, Plot no. IP-27-29, KIADB Industrial area, 1st Phase , Kudumalakunte village, Gowribidanur -Taluk, Chikkaballapur Dist, Karnataka- 5612018, India.		
API Lot No.	ORPC/191(Orphenadrine citrate) & 18GN60003(Paracetamol)		
Description of Pack (Container closure system)	Alu/Alu blisters packed in unit carton (10x10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9,12,18 &24 (Months)		
Batch No.	T001	T002	T003
Batch Size	100000 tablets	100000 tablets	100000 tablets
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	07-2021	07-2021	07-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

31.	Reference of previous approval of applications with stability study data of the firm (if any)	• Not provided
32.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol** Copy of GMP certificate No. 23/2020-DRAP(K) in the name of Saakh Pharma (Pvt.) Ltd, Plot # C-7/1, North West Industrial Zone, Port Qasim, Karachi, Pakistan. issued by DRAP is provided by the applicant & Valid up to 17-06-2022. **Orphenadrine citrate** Copy of GMP certificate No. DCD/SPL-1/CR-1852/2020-21) in the name of R L Fine Chem Pvt. Ltd, Plot no. IP-27-29, KIADB Industrial area, 1st Phase , Kudumalakunte village, Gowribidanur -Taluk, Chikkaballapur Dist, Karnataka- 5612018, India.issued by Drug Control Department, Karnataka is provided by the applicant & Valid up to 31/03/2022.
33.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
34.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has used UV spectrophotometer for dissolution and assay. Whereas in analytical method of Drug product manufacturer it's on HPLC.

35.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
36.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks OF Evaluator PEC-VI:

Sr.#	Section#	Observation
1.	**1.1**	• Firm has submitted 20,000 fee, dated 30-03-2020. Fee differential of R.s 10,000/- shall be submitted.
2.	**1.3.5**	• Approval letter of the section (Dosage form) in which manufacturing of the applied product is to be carried out needs to be submitted • GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
3.	**1.5.9**	Firm has provided approval of NORGESIC tablet approved by TGA, Australia, which is uncoated tablet. However, firm has applied for film coated tablet and perform the stability studies and CDP in film coated form. Justification required.
4.	**1.6.5**	Provided GMP certificates are expired for both drug substances(s) i.e. Paracetamol and Orphenadrine citrate.
5.	**3.2.S.4**	• Analytical Method verification studies for drug substance Paracetamol USP performed by Drug product manufacturer are missing. • Analytical Method verification studies for drug substance Orphenadrine citrate BP performed by Drug product manufacturer are missing. • **Batch analysis** Provide results of analysis of relevant batch(es) of both Drug Substance i.e Paracetamol + Orphenadrine citrate performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.
6.	**3.2.S.5**	Traceability of working standard provided by Drug substance manufacturer of Paracetamol is missing.
7.	**3.2.S.7**	• In stability studies of Drug substance manufacturer of Paracetamol data for 2-year real time stability studies has been provided. However as per COA DS manufacturer is claiming 3 years shelf life. 3 years real time stability data is required. • In stability studies of Drug substance manufacturer of Paracetamol data for accelerated stability studies shall be provided.
8.	**3.2.P.2**	• Pharmaceutical Equivalence have been Performed against Nuberol forte, which is different in composition than applied product. • As qualitative composition of the formulation is not similar to innovator / reference product, the drug-excipient compatibility studies shall be provided
9.	**3.2.P.2.2.1**	Firm has performed Comparative dissolution profile with product Nuberol forte, which is different in composition than applied product. Justification required. In provided CDP profile results Paracetamol/ Orphenadrine dissolution is 0.01 -0.02 % after 60 minutes. Whereas in Pharmaceutical equivalence results dissolution is 98.28 % in 0.1 N HCl . Justification required.
10.	**3.2.P.5**	Analytical method validation for finished drug product shall be provided.
11.	**3.2.P.8.**	• Stability studies data sheets are not in accordance with the raw sheets of data. • Firm has used UV spectrophotometer for dissolution and assay. Whereas in analytical method of Drug product manufacturer it's on HPLC. • In raw data sheets of UV spectrophotometer parameters of testing's and results are missing. • Documents for the procurement of API with approval from DRAP (in case of import) of both API's. • In stability studies data sheets API lot no are 40000290161whereas COA of batch no. ORPC/191(Orphenadrine citrate) & 18GN60003(paracetamol) are attached. Justification required

12.	**3.2.P.8.3**	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.
Decision: The Board deferred the case for clarification of the above cited observations.		

Agenda of Evaluator PEC-VIII (Mr. Usman)

49.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Pharmadic Laboratories (Pvt) Ltd, 16 KM, Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pharmadic Laboratories (Pvt) Ltd, 16 KM, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of GMP certificate No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020
	Evidence of approval of manufacturing facility	Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10710 dated 28-04-22
	Details of fee submitted	PKR30000 dated: 27.05.2022 bearing Deposit Slip No. 09713095356
	The proposed proprietary name / brand name	Darvin Forte 75mg/650mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tramadol HCL … 75mg Paracetamol ….. 650mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Opioid & Non-Opioid Analgesic
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tramadol/Paracetamol (uncoated tablet) 75 mg / 650 mg tablets is MHRA approved as an uncoated tablet. **Zentiva 75mg/650 mg, Tablet , Slovakia is mentioned as innovator/reference Product**
	For generic drugs (me-too status)	Tonoflex-P Forte (film coated) of M/S Sami Pharmaceuticals (Pvt) Ltd, Karachi
	Name and address of API manufacturer.	**Paracetamol (USP/BP):** M/s Saakh Pharma (Pvt) Ltd, Karachi. **GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022** **Certificate No. ZJ20170049**

		Tramadol HCL USP : M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 24 months for both API's namely **Paracetamol & Tramadol HCL USP .**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Tonoflex-P Forte Tablet 75/650 mg by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi by performing quality tests including Identification, water content, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is Tonoflex-P Forte Tablet 75/650 mg by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. **The F2 values are not found satisfactory.**
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Paracetamol (USP/BP):** M/s Saakh Pharma (Pvt) Ltd, Karachi. **GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022** **Certificate No. ZJ20170049**

	Tramadol HCL USP : M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.		
API Lot No.	Paracetamol : ZPAR18-143 Tramadol HCL : TDH0480218		
Description of Pack (Container closure system)	The proposed pack size of Darvin Forte Tablet is 1x10's in Alu—PVC Blister.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3, 6,9,12,18,24(Months)		
Batch No.	ACTD-TR001	ACTD-TR002	ACTD-TR003
Batch Size	1000 TABLETS	1000 TABLETS	1000 TABLETS
Manufacturing Date	10,2019	10,2019	10,2019
Date of Initiation	10-10-2019	10-10-2019	10-10-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• **Not Provided**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol (USP/BP):** M/s Saakh Pharma (Pvt) Ltd, Karachi. **GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022** **Certificate No. ZJ20170049** **Tramadol HCL USP :** M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Paracetamol (USP/BP):** Not Required **Tramadol HCL USP :** **Not Provided**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not Provided.**
Evaluation by PEC:		

1. Evidence of approval of applied formulation in reference regulatory authorities as defined by the registration Board shall be submitted. As the applied formulation in reference regulatory authorities is approved as "uncoated" tablets while the applicant has applied as film coated tablets
2. Provide certificate of analysis of relevant batch(es) of Drug Substance(s) (Paracetamol & Tramadol HCL) used in product development (By both Drug Substance and Drug Product manufacturer.
3. As per submitted data of comparative dissolution profile following points have been observed:
   - For Paracetamol:
     - Value of F2 factor is 46% in Buffer Acetate pH 4.5
     - Value of F2 factor is 38% in Phosphate Buffer pH 6.8
   - For Tramadol HCl:
     - value of F2 factor is 44% in 0.1N HCL
     - Value of F2 factor is 46% in Phosphate buffer pH 6.8

   Please justify scientifically.
4. Specificity testing in Analytical method validation has not been performed for the applied Product.

Decision: Since the applied product is approved as "uncoated tablet" in reference regulatory authorities while the applicant has applied for film coated tablet. Therefore, Registration Board decided to defer the case for evidence of approval of applied formulation in reference regulatory authorities/agencies as "film coated tablet" which were declared/approved by the Registration Board in its 275th meeting.

Agenda of Evaluator PEC-XIII

50.	Name, address of Applicant / Marketing Authorization Holder	Wilson's Pharmaceuticals, Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.
	Name, address of Manufacturing site.	Wilson's Pharmaceuticals, Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales.
	Dy. No. and date of submission	Form-5F Dy. No. 3336 dated 03-02-2022.
	Details of fee submitted	PKR 75,000/-: dated 07-01-2022.
	The proposed proprietary name / brand name	Colynol Multi Symptom Severe Cold Sachet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains; Paracetamol …….. 500mg Phenylephrine HCl …… 10mg Dextromethorphan HBr ……. 20mg
	Pharmaceutical form of applied drug	Sachet.
	Pharmacotherapeutic Group of (API)	Cough Suppressants and expectorants. (R05FB02)
	Reference to Finished product specifications	Manufacturer specifications.
	Proposed Pack size	10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Theraflu Multi Symptom Severe Cold Sachet. However, the same could not be found in USFDA data. Daily med has the same product as OTC product with the following disclaimer:

		Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.
	For generic drugs (me-too status)	Could not be confirmed.
	GMP status of the Finished product manufacturer	Inspection report of 24-01-2018. Not valid.
	Evidence of section approval.	Tablet (general) section approved vide No. F. 1-19/92-Lic (P1) dated 27-07-2015.
	Name and address of API manufacturer.	**Paracetamol:** Saakh Pharma (Pvt.) Ltd., C-7/1, North Western Industrial Zone. Port Qasim, Karachi. Copy of GMP certificate No. 83/2020-DRAP(K) of M/s Saakh Pharma (Pvt.) Ltd., C-7/1, North Western Industrial Zone. Port Qasim, Karachi issued by DRAP Karachi valid till 18/06/2022. **Dextromethorphan hydro bromide:** Onerio Chemicals (Pvt.) Limited, S. No. 475/P, At & Po Ekalbara – 391 440, Ta. Padra, Distt. Vadodara, Gujrat, India. Firm has submitted license to manufacture for sale of drugs in the name of M/s Onerio Chemicals (Pvt.) Limited, issued by the Food & Drug Administration Gujrat State India valid till 13-07-2022. **Phenylephrine Hydrochloride.** M/s Shenzhen Oriental Pharmaceutical Co., Ltd., No. 43, Dakeng Road, Tongle village, Longgang District, Shenzhen China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of all the three drug substances and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol (USP/BP/EP), Dextromethorphan HBr (USP/BP/EP) and Phenylephrine HCl (USP/BP/EP) is present respectively. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests impurities, specifications, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of the following drug substances as per Zone IV-a for both accelerated as well as real time conditions: **Paracetamol:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 12 months. (Batch No. 18GN60001, 18GN60002, and 18GN60003) **Dextromethorphan hydro bromide:** Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months.

		Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months. (Batch No. DX/B/054/12, DX/B/055/12 and DX/B/056/12) **Phenylephrine hydrochloride.** Not provided.
	Module-III (Drug Product):	The firm has submitted detail of description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the innovator product that is Theraflu Multi symptom Severe Col Sachet by performing quality tests (Assay). Assay of both the products are in acceptable range. CDP has not been performed because our applied dosage form is powder (sachet).
	Analytical method validation/verification of product	Method validation studies have been submitted including: system suitability, accuracy, and precision.

STABILITY STUDY DATA

Manufacturer of API	**Paracetamol:** Copy of GMP certificate No. 83/2020-DRAP(K) of M/s Saakh Pharma (Pvt.) Ltd., C-7/1, North Western Industrial Zone. Port Qasim, Karachi issued by DRAP Karachi valid till 18/06/2022. **Dextromethorphan hydro bromide:** Firm has submitted copy of license to manufacture for sale of drugs in the name of M/s Onerio Chemicals (Pvt.) Limited, issued by the Food & Drug Administration Gujrat State India valid till 13-07-2022. **Phenylephrine Hydrochloride.** Not provided.		
API Lot No.	**Paracetamol** (Batch No.19GN60228, Batch No. 19GN60222) **Dextromethorphan HBr** (Batch No. DX/L/017/18) **Phenylephrine HCl** (Batch No.PEH-180101Y1)		
Description of Pack (Container closure system)	Peach colored flavored powder packed in aluminum foil.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1200 sachet	1200 sachet	1200 sachet
Manufacturing Date	04-2020	05-2020	05-2020
Date of Initiation	22-05-2020	22-05-2020	22-05-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

37.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
38.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificates of: Paracetamol: Copy of GMP certificate No. 83/2020-DRAP(K) of M/s Saakh Pharma (Pvt.) Ltd., C-7/1, North Western Industrial Zone. Port Qasim, Karachi issued by DRAP Karachi valid till 18/06/2022. Guaifenesin: Copy of GMP certificate No. ZJ20180122 of Zhejiang Haizhou Pharmaceutical Co., Ltd., Linhai Industrial Zone, Linhai city Zhejiang China issued by China food & Drug Administration valid until 09-25-2023. Phenylephrine Hydrochloride. Not provided.
39.	Documents for the procurement of API with approval from DRAP (in case of import).	• **Paracetamol;** Copy of commercial invoice No. PRT/2019/0208 dated 30/03/2019 is submitted. Copy of commercial invoice No. PRT/2019/0197 dated 25/03/2019 is submitted. • **Dextromethorphan HBr;** Clearance certificate No. 794 dated 14-03-2019 mentioning 300 gm quantity of Dextromethorphan HBr EP, batch No. DX/L/017/18 attested by Assistant Director I&E is submitted by the firm. • **Phenylephrine HCl** Copy of clearance certificate attested by AD (I&E) DRAP, Islamabad dated 10/05/2018 along with commercial invoice No. SZ-1803039 dated 12/04/2018 with quantity of 308.25 Gram is submitted.
40.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
41.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
42.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
7.	1.3	Valid copy of DML and latest GMP certificate/inspection report conducted within last three years of the finished product manufacturer shall be provided.	
8.	1.6.5	• Valid copy of GMP certificate for drug substance manufacturer (Paracetamol) shall be submitted. • Valid copy of GMP certificate drug substance manufacturer (Phenylephrine Hydrochloride) shall be submitted. • Valid copy of manufacturing license or GMP certificate for the drug substance manufacturer (Dextromethorphan	

		HBr) issued by concerned regulatory authority shall be submitted.	
9.	2.3.R.1	• Provide blank master production document/batch manufacturing record to be used during the commercial manufacturing of the applied product. • Provide copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
10.	3.2.S.4.2	• Analytical method used for drug substance (Paracetamol) used by the drug Product manufacturer shall be submitted. • Analytical method used for drug substance (Dextromethorphan HBr) used by the drug Product manufacturer shall be submitted. • Analytical method used for drug substance (Phenylephrine hydrochloride) used by both the drug substance manufacturer and drug Product manufacturer shall be submitted.	
11.	3.2.S.4.3	• Verification studies of the drug substance (Paracetamol) performed by the drug product manufacturer shall be submitted. • Verification studies of the drug substance (Dextromethorphan HBr) performed by the drug product manufacturer shall be submitted. • Verification studies of the drug substance (Phenylephrine hydrochloride) performed by the drug product manufacturer shall be submitted.	
12.	3.2.S.4.4	Provide results of analysis of relevant batch(es) of all the three Drug Substances (Paracetamol, Dextromethorphan HBr & Phenylephrine hydrochloride) performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	
13.	3.2.S.8.3	Stability study data for the drug substance (Phenylephrine hydrochloride) from concerned manufacturer shall be submitted.	
14.	3.2.P.8.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	

Decision: The Board deferred the case for the following:

- **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**
- **Submission of valid copy of DML and latest GMP certificate/inspection report conducted within last three years of the finished product manufacturer shall be provided.**
- **Submission of valid copy of GMP certificate for drug substance manufacturer (Paracetamol) shall be submitted.**
- **Submission of valid copy of GMP certificate drug substance manufacturer (Phenylephrine Hydrochloride) shall be submitted.**

- **Submission of valid copy of manufacturing license or GMP certificate for the drug substance manufacturer (Dextromethorphan HBr) issued by concerned regulatory authority shall be submitted.**
- **Submission of blank master production document/batch manufacturing record to be used during the commercial manufacturing of the applied product.**
- **Submission of copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.**
- **Submission of analytical method used for drug substance (Paracetamol) used by the drug Product manufacturer shall be submitted.**
- **Submission of analytical method used for drug substance (Dextromethorphan HBr) used by the drug Product manufacturer shall be submitted.**
- **Submission of analytical method used for drug substance (Phenylephrine hydrochloride) used by both the drug substance manufacturer and drug Product manufacturer shall be submitted.**
- **Verification studies of the drug substance (Paracetamol) performed by the drug product manufacturer shall be submitted.**
- **Verification studies of the drug substance (Dextromethorphan HBr) performed by the drug product manufacturer shall be submitted.**
- **Verification studies of the drug substance (Phenylephrine hydrochloride) performed by the drug product manufacturer shall be submitted.**
- **Submission of results of analysis of relevant batch(es) of all the three Drug Substances (Paracetamol, Dextromethorphan HBr & Phenylephrine hydrochloride) performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.**
- **Submission of stability study data for the drug substance (Phenylephrine hydrochloride) from concerned manufacturer shall be submitted.**
- **Reference of previous approval of applications with stability study data of the firm shall be submitted.**

Agenda of Evaluator PEC-II

51.	Name, address of Applicant / Marketing Authorization Holder	**M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25927 dated 17-09-2021
	Details of fee submitted	PKR 30,000/-: dated 07/09/2021 PKR 45,000/-: dated 25/10/2021
	The proposed proprietary name / brand name	**Provas Advance 500mg Tablet** **Alternate brand name: PROVAS NOVO 500mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol ……. 500mg
	Pharmaceutical form of applied drug	White to off-white colored capsular shaped film coated tablet, break line on one side and other side is plain

	Pharmacotherapeutic Group of (API)	NSAID ATC Code: N02BE01
	Reference to Finished product specifications	USP
	Proposed Pack size	10's, 20's, 30's, 50's & 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Panadol Advance 500mg Tablet, M/s. GSK, approved by MHRA of UK
	For generic drugs (me-too status)	Not applicable
	GMP status of the Finished product manufacturer	GMP certificate issued dated: 11-08-2020
	Name and address of API manufacturer.	**Name:** HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD SHENZHOU PLANT (shortened as Jiheng Shenzhou) **Address:** Southeast Xijingming Village Donganzhuang Township, Shenzhou County Henshui City, Hebei Province, CHINA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, characterization, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity J, K, F, individual impurity and total impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 Months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is PANADOL ADVANCE 500mg tablet by M/s. GSK. CDP has been performed against the same brand that is PANADOL ADVANCE 500mg tablet by M/s. GSK in Acid media (pH 1.2-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including Linearity, Accuracy & Precision including Repeatability & Specificity.
STABILITY STUDY DATA		

Manufacturer of API	HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD SHENZHOU PLANT, CHINA		
API Lot No.	31709016		
Description of Pack (Container closure system)	Alu/PVC Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-07	Lab-08	Lab-09
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	14-4-2021	14-4-2021	14-4-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of last onsite panel inspection for instant dosage form conducted during last two years i.e. EMPOLI (Empagliflozin) 10mg & 25mg Tablets which was presented in 290th meeting of the registration board & hence approved & registered by registration board Date of inspection: 13th June 2019. The inspection report confirms following points • The HPLC software is 21CFR Compliant. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HE20180054 issued by Hebei CHINA FOOD AND DRUG ADMINISTRATION valid till 08/07/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (Invoice# 1708ZP03 dated 19th October 2017 with received quantity i.e. 5000 kgs) for the purchase of Paracetamol from M/s Hebei Jiheng Shenzhou Pharmaceutical Co., Ltd. China with attestation of DRAP dated 01-11-2017
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[II]:

- Regarding justification of specifications of drug product, firm has submitted as under:
  "The dissolution parameters and testing procedure is as per USP Pharmacopeia but as the Paracetamol is rapidly dissolving drug and falls in BCS Class I, we stringent the dissolution specifications from 30 minutes to 10 minutes
  The selection of specified time for Dissolution is based on the BCS classification of API, as the drug is independent over physiological pH range (i-e from 1.2 to 6.8) and ·as per USP General chapter <1092>, the dissolution of rapidly dissolving product is achieved within 15 minutes therefore we established our dissolution time within 10minutes."

- Firm has submitted following comparison between the applied formulation and conventional paracetamol tablet already available in market:

Parameters	**PROVAS Novo 500mg Tablet**	**Paracetamol 500mg Tablet**
Dosage Form	Tablet	Tablet
Dosage Design	Immediate release film coated tablet	Immediate release uncoated tablet
Route of Administration	Oral	Oral
Dosage Strength	500mg	500mg
Pharmacokinetics	The special technology allows **PROVAS Novo 500mg Tablet** to begin dissolving in 5 minutes and start to relieve pain within 15 minutes	Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion
Patient's Acceptance & Compliance	• Capsular shape makes it easy to swallow • Bitter taste of Paracetamol is masked through film coating • Quick & Effective Pain Relief Stomach Friendly	• Round shape makes it difficult to swallow • Bitter Taste Delayed Pain Relief
Technology Used	**PROVAS Novo 500mg Tablet** is a Paracetamol formulation that contains an advance technology to rapid the onset of action	**Paracetamol 500mg Tablet** formulated using a conventional wet granulation process
Key Features	• It has unique delivery system as **PROVAS Novo 500mg Tablet** is a Paracetamol formulation that contains a rapid dispersion and dissolution technology which breakdown Paracetamol tablets in the stomach so that the drug is absorbed fast and pain relief can start within 15 minutes after ingestion • The technology contains three main ingredients viz.: ○ **Alginic Acid** draws fluid from the stomach into the tablet causing it to swell and break apart ○ **Calcium Carbonate** works together with Alginic Acid to boost disintegration of the tablet ○ **Crospovidone** acts as a super-disintegrant due to its ability to dissolve well in water • The absorption of Paracetamol occurs in the small intestine and as such is dependent on the rate of emptying of stomach contents into the small intestine and is therefore not associated with gastric irritation. The technology used in **PROVAS Novo 500 mg** Tablet increases gastric emptying time of the drug. • **PROVAS Novo 500mg Tablet** with this advance technology disperses up to five times faster than standard paracetamol tablets Suitable for all such patients requiring low sodium content in their diet	Onset of action is slow, as peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion

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

3.2.P.5.1	• Limits for disintegration test i.e., NMT 30 minutes are inconsistent with the limits of dissolution test i.e., NLT 80% (Q) in 10 minutes.	We set disintegration specification according to USP general monograph for Disintegration <701> which specifies NMT 30minutes for film coated tablets. Our product is fast dissoving with a dissolution specs of NLT 80% (Q) in 10 minutes and disintegration time of our product is also found within 01 minute which co relates with dissolution. We have revised the specification of DT from NMT 30 minmutes to NMT 10 minutes.
3.2.P.6	• Submitted COA of working standard declares the "Valid till" date as January 2021, whereas trial batches have been manufactured and analyzed subsequent to this date. • Submitted COA of working standard is of BP grade, whereas drug product specifications have been claimed as per USP monograph.	Firm has submitted new COA of working standard, which had been standardized in January 2021 having validity date as of Jan, 2022. Firm has submitted that the working standard complies with both & USP monograph of Paracetamol, since both the monographs are harmonized.

Decision of 320th meeting: The Board was apprised that the firm has applied for two products with the similar formulation that is Paracetamol, film coated tablet with slight difference in method of manufacturing and qualitative composition. The Board after due deliberation decided to defer the case for clarification whether an applicant can apply for registration of more than two products having same composition or otherwise.

Firm's response:

PANADOL Conventional Tablets	**PANADOL ADVANCE & PROVAS NOVO 500 mg Tablet**
1) Marketing Authorization Status:	
Panadol 500mg is marketed by GlaxoSmithKline Consumer Healthcare (UK) Trading Limited bearing **Marketing authorization number(s)** PL 44673/0081 **Reference attached** https://www.medicines.org.uk/emc/product/6474/smpc#gref	Panadol advance 500mg is marketed by GlaxoSmithKline Consumer Healthcare (UK) Trading Limited bearing **Marketing authorization number(s)** PL 44673/0080 **Reference attached** https://www.medicines.org.uk/emc/product/6512/smpc#gref
2) Pharmacokinetics	
-	• Human scintigraphy data demonstrate that Panadol Advance 500 mg Tablets generally start to disintegrate by 5 minutes post dose in the stomach • 37% faster compared to standard paracetamol tablets • It dissolves in 5 minutes and start to relieve pain within 15 minutes **Reference attached** https://www.medicines.org.uk/emc/product/6512/smpc#gref
3) Disintegration time	
Disintegration Time: within 15minutes	**Disintegration Time:** within 10minutes
Dissolution	
Dissolution Test: NLT 80% (Q) in 30minutes	**Dissolution Test: NLT 80% (Q)** in 10minutes
4) Technology/Formulation	

Standard Paracetamol tablet formulated using conventional wet granulation process	Optizorb technology is used to provide rapid onset of action and allows it to dissolve in 5minutes and start to relive pain with in 15minutes
5) Excipients	
-	• Contain a unique disintegrant system which consist on following three excipients: ▪ **Alginic acid** which draws fluid from the stomach into the tablet causing it to swell and break apart ▪ **Calcium Carbonate** works together with Alginic Acid to boost disintegration of the tablet **Crospovidone** acts as a super-disintegrate due to its ability to dissolve well in water

Decision:The Board discussed that the applicant already have the registration of formulation containing Paracetamol 500mg as immediate release tablet whereas the firm has applied for the same formulation having different excipients and there is no change in strength, dosage form, salt form, drug delivery system etc. Considering the fact that different excipients are used in the applied product and already approved formulation, the Board deferred the case for clarification from applicant and then further deliberation.

52.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals. 23-Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals. 23-Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 22083 dated 03-08-2022
	Details of fee submitted	Rs.30,000/- dated 27-07-2022
	The proposed proprietary name / brand name	**Bripara 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol USP…..500mg
	Pharmaceutical form of applied drug	tablet
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 500mg Tablets by M/s Dr. Max Pharma Netherlands.
	For generic drugs (me-too status)	Panadol 500mg Tablets Manufactured by M/s Pharmatec Pakistan (Pvt) Ltd and marketed by M/s GlaxoSmithKline Pakistan. (Reg. No.: 101138)

	GMP status of the Finished product manufacturer	Renewal of DML granted dated 12-01-2022.
	Name and address of API manufacturer.	M/s Zenith Chemical industry Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Paracetamol 500mg Tablets of M/s GlaxoSmithKline Pakistan.
	Analytical method validation/verification of product	Method validation studies have submitted including, system suitability, specificity, linearity, accuracy, precision repeatability, Intermediate precision and robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s Zenith Chemical industry Lahore.		
API Lot No.	ZPAR20-350		
Description of Pack (Container closure system)	Alu-PVC blister packed		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 & 12 (Months)		
Batch No.	B1	B2	B3
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	04-2021	04-2021	04-2021

No. of Batches		03
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	• --
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of certificate of Good Manufacturing Practices (GMP) issued by Hebei Food and Drug Administration. (valid till 08-07-2023).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record, analytical record
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section #.	Deficiencies
3.2.S.4	Drug substance analytical method verification studies shall be submitted by M/s British pharmaceuticals.
3.2.P.1	Drug product description declares it as film coated tablet whereas submitted composition is for uncoated tablet.
3.2.P.2.2.1	Clarification shall be submitted for reporting f2 factor value as 100 for CDP studies in three dissolution mediums of pH 1.2,4.5 & 6.8.
3.2.P.5.3	Performance of accuracy & precision parameter during analytical method verification studies has not been conducted as per recommendations of ICH Q2 (R1) guidelines.
3.2.P.8.3	• Document for the procurement of drug substance shall be submitted. • Complete analytical record for the performance of dissolution test during stability studies shall be submitted. • Complete raw data sheets wherein details of sample solution preparation, standard solution preparation, weight of standard & sample and calculation formula applied for the test Assay & Dissolution test shall be submitted for complete stability studies.

Decision of 320thmeeting: Deferred for;

- Submission of drug substance analytical method verification studies by M/s British pharmaceuticals.
- Clarification since drug product description declares it as film coated tablet whereas submitted composition is for uncoated tablet.
- Clarification shall be submitted for reporting f2 factor value as 100 for CDP studies in three dissolution mediums of pH 1.2,4.5 & 6.8.
- Performance of accuracy & precision parameter during analytical method verification studies has not been conducted as per recommendations of ICH Q2 (R1) guidelines.
- Performance of accuracy & precision parameter during analytical method verification studies has not been conducted as per recommendations of ICH Q2 (R1) guidelines.
- Submission of document for the procurement of drug substance shall be submitted.

- Submission of complete analytical record for the performance of dissolution test during stability studies.
- Submission of complete raw data sheets wherein details of sample solution preparation, standard solution preparation, weight of standard & sample and calculation formula applied for the test Assay & Dissolution test for complete stability studies.

Firm's response:

Section #.	Deficiencies	Firm's response
3.2.S.4	• Drug substance analytical method verification studies shall be submitted by M/s British pharmaceuticals.	• Submitted
3.2.P.1	Drug product description declares it as film coated tablet whereas submitted composition is for uncoated tablet.	Drug product is uncoated/core tablet. It is typographical error. Description is revised
3.2.P.2.2.1	Clarification shall be submitted for reporting f2 factor value as 100 for CDP studies in three dissolution mediums of pH 1.2,4.5 & 6.8.	Drug product is uncoated/core tablet and formulation is same as of innovator's product so dissolution behavior observed was similar to innovator's product and value of f2 factor observed was 100.
3.2.P.5.3	Performance of accuracy & precision parameter during analytical method verification studies has not been conducted as per recommendations of ICH Q2 (R1) guidelines.	Submitted
3.2.P.8.3	• Document for the procurement of drug substance shall be submitted. • Complete analytical record for the performance of dissolution test during stability studies shall be submitted. • Complete raw data sheets wherein details of sample solution preparation, standard solution preparation, weight of standard & sample and calculation formula applied for the test Assay & Dissolution test shall be submitted for complete stability studies.	• Copy of commercial invoice no. 00004/0421 dated 01-04-2021 for procurement of 500Kg of Paracetamol from M/s Zenith Chemical Industries. • Submitted.

Decision: Approved

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Furthermore, the Board decided that the manufacturer shall submit Comparative Dissolution Profile again against the innovator's product with the complete calculations for F2 and F1 factors before issuance of registration letter.**

Agenda of Evaluator PEC-XVI

53.	Name, address of Applicant / Marketing Authorization Holder	M/s SWERA Pharmaceuticals Address: Plot No. 27, Street No. S-4, Industrial Area Rawat.
	Name, address of Manufacturing site.	M/s SWERA Pharmaceuticals Address: Plot No. 27, Street No. S-4, Industrial Area Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1009 dated 11/01/2022
	Details of fee submitted	PKR 30,000/-: Slip No. Slip No.9859557406
	The proposed proprietary name / brand name	TP-DUX 325/37.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol ……325mg Tramadol HCL …..37.5mg
	Pharmaceutical form of applied drug	Off-white, Oval shaped, Film Coated Tablets
	Pharmacotherapeutic Group of (API)	Narcotic Analgesic (Tramadol HCL) Analgesic (Acetaminophen)
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved, Consilient Health Ltd No. 1 Church Road, Richmond upon Thames, Surrey, TW9 2QE, UK.
	For generic drugs (me-too status)	Rama-D Tablets, GLOBAL Pharma Isb,
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/S Saakh Pharmaceuticals, Plot No. C-7/1, NWIZ, Karachi, Pakistan. M/S Lucent Pharma, Plot # W-109 Street No.1 Sanathnagar, Hyderabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol & Tramadol HCl is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance submitted.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (T001, T002, T003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is RAMA –D 325 /37.5mg tablet by GLOBAL Pharma, Isb CDP has been performed against the same brand that is RAMA-D 325/37.5mg tablet by Global Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/S Saakh Pharmaceuticals, Plot No. C-7/1, NWIZ, Karachi, Pakistan. M/S Lucent Pharma, Plot # W-109 Street No.1 Sanathnagar, Hyderabad.		
API Lot No.	18GN60003, APL 0210119		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	27-09-2021	27-09-2021	27-09-2021
No. of Batches	03		

Administrative Portion		
43.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
44.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	No Evidence provided by firm.
45.	Documents for the procurement of API with approval from DRAP (in case of import).	No Evidence provided by firm.
46.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
47.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Complied
48.	Record of Digital data logger for temperature and humidity monitoring of	Not provided

	stability chambers (real time and accelerated)	

Remarks OF Evaluator: Following deficiencies / Shortcomings were observed during the evaluation of Dossier, A deficiency letter dated 19-09-2022 is communicated to firm, Reply of which is still awaited.

1. GMP certificate of manufacturing site (API Manufacturer) for Tramadol Hcl is missing, which is required.
2. Firm has claimed that process of coating under controlled and sterile environment, which needs clarification whether sterile area is required for coating of this product or not.
3. COA of Paracetamol API batch No. 21GN60186 is submitted, COA conducted for same batch by Finished product manufacturer is required.
4. The stability data of Paracetamol API conducted by API manufacturer, M/s Saakh Pharma, Karachi for all three provided batches, (18GN60001,18GN60002,18GN60003) does not depict quantitative results of Test for organic impurities and related substance, i-e 4-amino phenol.
5. The comparative study results of applied product TP-DUX with comparator product Rama-D Tablet Mention Limit of salicylic acid as NMT 3.0 % which needs clarification as such impurity is not present in API specifications.
6. The applied Finished product specification is USP specification, the dissolution specification is given as NLT 80% (Q) of labeled amount in 30 minutes (USP) in 0.1 N HCl with analytical procedure with HPLC, however the comparative dissolution data provided, the analytical method used is Ultraviolet Spectroscopy, which needs clarification.
7. The apparatus mentioned for dissolution as per USP type II with 50 RPM whereas per submitted CDP firm has conducted on 100 RPM, Clarification is needed.
8. The CDP data/results of applied and comparator product does not qualify finished good specification for dissolution profile at 0.1 N CL medium within 30 minutes.
9. The results /data submitted by firm for manufacturing process validation does not specify the method of assay to determine Paracetamol and Tramadol Hcl during manufacturing process validation studies.
10. Stability study data of 3 months is provided for both accelerated and real time stability studies however 06-month stability study data is required.
11. The provided stability data for three batches T001, T002 and T003 depict assay of Finished drug product as whole instead of individual APIs within finish Product with their specific assay results of each API at each time point.
12. Firm has mentioned that they have attached GMP of SAAKH Pharma and Aurobindo Pharma, whereas per 3.2.S.2.1 the source of API mentioned for Tramadol is M/s Lucent Pharma, Hyderabad, India. Clarification is needed.
13. Import invoice of API, Tramadol Hcl (API) dully attested by DRAP is not provided.
14. GMP certificate of manufacturing site for Tramadol HCl is not provided.
15. Record of Digital Data logger for Temperature and humidity monitoring for stability chamber is not provided.
16. Firm has not provided chromatograms generated during the stability study testing (Assays and Dissolution testing) instead firm has provided UV graphs for absorption , which needs clarification whether firm has conducted assay as per USP monograph ,i-e HPLC method or UV method.

Decision: The Board deferred the case for clarification of above mentioned points.

Agenda of Evaluator PEC-XII (Mr. Zubair)

54.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale

		☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13224 dated 30/05/2022
	Details of fee submitted	PKR 75,000/-: dated 26/05/2022
	The proposed proprietary name / brand name	Tramacet 75mg/650mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tramadol HCl……...75mg Paracetamol ……650mg
	Pharmaceutical form of applied drug	Blue colored, oblong plain film coated tablet
	Pharmacotherapeutic Group of (API)	Opiate analgesic & NSAIDS
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's, 2x10's, 3x10's, As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tramadol/Paracetamol 75 mg / 650 mg Tablets by M/s Aspire Pharma Ltd. UK.
	For generic drugs (me-too status)	Tonoflex-P Forte tablet by M/s Sami Pharmaceuticals, Reg. No. 094798
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 70/2021-DRAP (FID/2061717-540) dated 08-09-2021.
	Name and address of API manufacturer.	**For Tramadol** M/s Proto Chemicals AG Tschachen 2,8756 Mitlödi (Glarus Süd), Switzerland. **For Paracetamol** M/s Carry For Pharmaceutical Private limited Plot. #: E-81, North Western industrial Zone. Port Qasim,Karachi, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Tramadol & paracetamol is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**For Tramadol HCl** Stability study conditions: Real time: 30°C ± 2°C/75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (E5846, E5861, E5862) **For Paracetamol**

		Stability study conditions: Real time: 30°C ± 2°C/65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (CPCM1908-001, CPCM1908-002, CPCM19010-003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure (including dissolution testing at acidic, acetate and buffer media), batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Tonoflex-P Forte of M/s Sami Pharmaceuticals by performing only Identification and Assay tests. CDP has been performed against the same brand that is Tonoflex-P Forte tablet by Sami Pharmaceuticals in Acidic media (pH-1.2), Acetate Buffer(pH-4.5) & Phosphate Buffer (pH 6.8). The values for f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**For Tramadol** M/s Proto Chemicals AG, Tschachen 2, 8756 Mitlödi (Glarus Süd), Switzerland. **For Paracetamol** M/s Carryfor Pharmaceuticals (Pvt) limited, Plot. #: E-81, North Western Industrial Zone, Port Qasim, Karachi.		
API Lot No.	Not Mentioned		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTP001	TTP002	TTP003
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	16-11-2021	17-11-2021	18-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**For Tramadol HCl** Copy of GMP certificate No. 20-0286 issued by Swiss agency for Therapeutic Products. **For Paracetamol** Copy of GMP certificate No.149/2020-Drap (K) dated 16-11-2020 issued by Drug Regulatory authority of Pakistan.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of DRAP attested invoice no. CS-21/02668 dated 01/04/2021 for Tramadol HCl 150kg is submitted. • Copy of local sales tax invoice No. 378 dated 10-10-2021 for Paracetamol 1000kg is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted the audit trail of 03 days for HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Observations Communicated	Response by the applicant on WhatsApp
i.	Submit copy of valid DML	Copy of DML No. 000789 renewed w.e.f. 03-02-2019 is submitted. However, the name of manufacturer in previous DML was **M/s Wimits Pharmaceuticals** while in new DML, it is **M/s Wimits Pharmaceuticals (Pvt.) Ltd.**
ii.	Submit clarification regarding out of limit Relative Standard Deviation RSD of Accuracy testing in verification of analytical procedures for Tramadol HCl.	The firm has submitted the revised RSD limits for verification of analytical procedures.
iii.	Submit clarification as Assay specification limits used in drug substance analysis of Paracetamol performed by drug product manufacturer are in accordance with BP monograph (99-101%) while in stability study data Assay specification limits are as per USP monograph (98-102%).	The firm submitted that the supplier complies with both BP & USP monograph and they had followed more stringent limit for the analysis i.e. 99-101%.
iv.	Clarification of not submitting compatibility studies as there is difference in qualitative formulation of applied product and Innovator product.	The firm has submitted the tabulated results of compatibility studies.
v.	Submit Pharmaceutical Equivalence as per pharmacopoeia monograph of the product.	The submitted Pharmaceutical Equivalence does not include Uniformity of Dosage Unit Test.
vi.	Maximum holding time of bulk before final packing is not submitted.	The firm submitted that the batch is processed right after dispensing and the bulk is not held for too long and batch is completed in 24hrs.
vii.	APIs lot no. is not indicated in stability study data.	The firm has submitted the revised stability data sheet indicating API Lot No. However, the mentioned lot of Tramadol HCL is different from the lot tested by drug product manufacturer.
viii.	Submitted DRAP attested invoice of Tramadol HCl is from Chemo S.A. Lugano Branch, Via F. Pelli 17, P.O. Box 6901, Lugano, Switzerland while the manufacturer of Tramadol HCl as per dossier is M/s Proto Chemicals AG, Tschachen 2, 8756 Mitlödi (Glarus Süd), Switzerland.	The firm submitted that Chemo S.A. Lugano is trader while Proto Chemicals is API manufacturer.
ix.	API lot numbers are not mentioned on local sales invoice of Paracetamol.	The firm has submitted the revised sales tax invoice indicating batch number of API. However, the invoice indicates the manufacturing date of API as **09-12-2021** while the record of trial batch of drug product manufactured from this API indicates the manufacturing date as **November, 2021**.
x.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing are not submitted.	The firm has submitted the audit trail of 03 days for HPLC.

Decision: The Board deferred the case for following points;

- **Clarification since the firm has submitted the invoice indicating batch number of Paracetamol, however, the invoice indicates the manufacturing date of Paracetamol (drug substance) as 09-12-**

	2021 while the record of trial batch of drug product manufactured from this lot indicates that the manufacturing date is November, 2021. • **Clarification since the firm has submitted the revised stability data sheet indicating th Lot No of Tramadol HCl, however, the mentioned lot of Tramadol HCl is different from the lot used for the product development.**

Agenda of Evaluator PEC-IV

55.	Name, address of Applicant / Importer	M/s INAYA TRADERS Flat no. 1, 1st floor, Plot no. A-152 Block-8, KAECHS, Karachi.
	Details of Drug Sale License of importer	**License No:** 0238 **Address:** Flat no. 1, 1st floor, Plot no. A-152 Block-8, KAECHS, Karachi. **Validity:** 21-June-2024
	Name and address of marketing authorization holder (abroad)	Shouguang Fukang Pharmaceuticals Co., Ltd Address: No.666 Donghuan Road, Shounguang City Shandong Province, P.R. China.
	Name, address of manufacturer(s)	Shouguang Fukang Pharmaceuticals Co., Ltd Address: No.999 Wensheng East road, Shouguang City Country: P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)** • Original legalized COPP (Certificate# ShanDong20222004) issued by Shandong Provincial Drug Adminstration issued on May,16th , 2022 • Free Sale status: The COPP endorses the free sale status of the applied product in China GMP status: COPP Specified that certifying authority arrange Periodic inspection of manufacturing plant and facility and operations confirms to GMP requirements. Drug manufacturing License: legalized copy of DML No# Lu 20160126 submitted and valid till October ,26,2025
	Details of letter of authorization / sole agency agreement	Sole agency agreement has been submitted with M/s Shouguang Fukang Pharmaceuticals Co., Ltd Dated:30-05-2022 (Copy)
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26228 dated: 16-09-2022
	Details of fee submitted	PKR 150,000/- Deposit slip # 2179283144

	The proposed proprietary name / brand name	**PARACETAMOL 500MG Tablet B.P**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Paracetamol…….500mg
	Pharmaceutical form of applied drug	Uncoated Tablet
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Reference to Finished product specifications	B.P
	Proposed Pack size	20 x 10's & 1000's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Paracetamol 500mg Tablets of Fourrts (UK) Pharmacare Ltd MHRA Approved Actavis Paracetamol 500mg Tablets of Fourrts (UK) Pharmacare Ltd MHRA Approved
	For generic drugs (me-too status)	Panadol 500mg of M/ GSK
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Hebei Jiheng Pharmaceuticals Co., LTD Address: No. 1Weiwu Street, Hengshui Industrial Park, Hebei Province, China.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 48 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months. Batches: (011608001, 011608002, 011608003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against Paracetamol 500mg Tablet by GSK (190312) by performing quality tests (Identification, Average weight, related substances, microbial limit, Assay, Dissolution, Uniformity of weight). CDP has been performed against the same brand by in Acid media (pH 1.2) & Acetate buffer 4.5 pH and

		Phosphate Buffer (pH 6.8) . The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies of the drug product.
	Container closure system of the drug product	PVC and Aluminium foil
	Stability study data of drug product, shelf life and storage conditions	Accelerated stability studies have been conducted at 40 ^{o}C ±2 ^{o}C and 75%±5% RH for 06 months. Real time stability studies conducted at 30 ^{o}C±2 ^{o}C and 65% ± 5% RH for 36months. Batches: (180611, 180612, 180613)

Evaluation by PEC:

S.No	Section	Shortcoming communicated	
1.	1.3.1	Name and address of marketing authorization holder (abroad)	Submitted
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Firm submitted analytical verification studies of of drug substance.
3.	3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture	Firm submitted Certificate of analysis by both drug substance manufacturer and drug product manufacturer.
4.	3.2.P.2.2.1	• Submit details of manufacturer, marketing authorization including country of origin of product against which pharmaceutical equivalence and Comparative dissolution profile conducted. • F1 or F2 calculation for comparative dissolution not submitted.	Paracetamol 500mg tablet manufactured by Accord Healthcare Ireland Ltd Batch No# 190312 Mfg date: 2019/04 Exp date: 2022/04 **(In initial dossier firm submitted that pharmaceutical equivalence and CDP was conducted against Product of GSK in reply they submitted that pharmaceutical equivalence and CDP was conducted against Paracetamol 500mg tablet manufactured by Accord Healthcare Ireland Ltd)** • F2 calculations submitted.

Decision: The Board deferred the case for clarification since in initial dossier firm submitted that pharmaceutical equivalence and CDP was conducted against Product of GSK in reply they submitted that

pharmaceutical equivalence and CDP was conducted against Paracetamol 500mg tablet manufactured by Accord Healthcare Ireland Ltd.		
56.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17868 dated 20-06-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 2746758563
	The proposed proprietary name / brand name	Panadol Extra Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol……. 500mg Caffeine….. 65mg
	Pharmaceutical form of applied drug	Oral (Tablet)
	Pharmacotherapeutic Group of (API)	Analgesics and Psychoactive drug.
	Reference to Finished product specifications	USP/BP specifications
	Proposed Pack size	**10x10's tablets**
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Panadol Extra by GSK (GlaxosmithKline), UK Approved in UK.
	For generic drugs (me-too status)	Panadol Extra GSK (GlaxosmithKline). Pakistan
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conducted on 19-03-2019
	Name and address of API manufacturer.	**Paracetamol:** Citi Pharma Pvt Ltd 3.5-Km, Head Balloki Road, Phool Nagar Kasur- Pakistan. **Caffeine:** Aarti Industries Limited 1. Plot No D-53, phase II, M.I.D.C Kalyanshil RD Dombival (East) Thane 421204 Maharashtra state, India. 2. K-17/18/19, M.I.D.C, tararpur, Distict, Thane.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of **Paracetamol and** Caffeine is present in BP. The firm as submitted detail of nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Paracetamol:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (PGP14-37, PGP14-38, PGP14-39) **Caffeine:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (C-3011 C-3076, C-3115)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Panadol Extra Tablets by M/s GSK (GlaxosmithKline). Pakistan performing quality tests (Identification, Weight variation, Disintegration, Assay, Dissolution). CDP has been performed against the same brand that is Panadol Extra Tablets by M/s GSK (GlaxosmithKline). Pakistan in Acid media (pH-1.2),Acetate Buffer(pH-4.5) & Phosphate Buffer (pH 6.8)..
	Analytical method validation/verification of product	

STABILITY STUDY DATA			
Manufacturer of API	Paracetamol: M/s Citi Pharma Private Limited Lahore. Caffeine: Aarti Industries Limited		
API Lot No.	**Caffeine:** **Paracetamol:**		
Description of Pack (Container closure system)	**10X10's Blistered in ALU-PVC packed in standard unit carton provided with leaflet inside.**		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRA-PE001	TRA-PE002	TRA-PE003
Batch Size	10,000 Tablets	10,000 Tablets	10,000 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-2022	01-2022	01-2022
No. of Batches	03		
Administrative Portion			

7.	Reference of previous approval of applications with stability study data of the firm (if any)	
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** Copy of cGMP certificate on the basis of evaluation conducted on 17-12-2020 and valid for 2 years **Caffeine**: Copy of GMP certificate No. NEW-WHO-GMP/KD/88375/2019/11/30185 issued by Food and Drug Administration Mahrashtra India-valid for 19-11-2022
9.	Documents for the procurement of API with approval from DRAP (in case of import).	**Paracetamol:** Purchase documents Invoice No# F20-34 Dated: 11-08-2021 of Batch No # PGP21-513
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Remarks OF Evaluator: Firm submitted NOC as follows:

M/s GlaxoSmithKline Consumer health Pakistan Limited 35-Dockyard Road, West Whraf –Karachi-Pakistan has provided no objection certificate for utilization of Panadol brand name as under :-

*"We, owners of the **"Panadol"** brand name since may decades globally and in Pakistan for last 45 years, would like to manufacture our following products at **"Citi Pharma Private Limited"** under the DRAP's Contract manufacturing policy:*

S.No.	***Brand Name***
1.	*Panadol Extra Tablets*
2.	*Panadol Migraine tablets*
3.	*Panadol Muscle Relaxant tablets*

*Further to this, Please note that we have no objection to the use of the brand Name **"Panadol"** for the aforementioned products, applied by Citi Pharma for the registration on contract manufacturing on behalf of GlaxoSmithKline consumer Healthcare Limited Pakistan."*

S.No	Section	Shortcomings Communicated
1.	1.6.5	Submitted GMP certificate of different site than documents submitted for drug substance (Caffeine)
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active (Caffeine)Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) (Paracetamol and Caffeine)shall be submitted.
5.	3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / Active Pharmaceutical Ingredient (Paracetamol and Caffeine) manufacture.
6.	3.2.S.5	COA of primary / secondary reference standard including source and lot number for Caffeine shall be provided.

7.	3.2.P.2.2.1	• 6 units are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution. • F2 calculations for paracetamol and caffeine not submitted.
8.	3.2.P.3.5	Submitted Process validation protocol are general not product related. Clarification is required.
9.	3.2.P.5.1	• Specification claimed are USP while in section 1.5.6 applied as B.P. Clarification is required. • Justify your acceptance criteria for dissolution test as NLT 75% after 60 minutes of the labeled amount of paracetamol and caffeine while USP has specified as NLT 75% (Q) of the labelled amounts of acetaminophen and caffeine is dissolved.
10.	3.2.P.5.3	Analytical Method Verification studies performed by the Drug Product manufacturer for drug product shall be submitted.
11.	3.2.P.8	• Stability studies of three (03) months submitted. • Documents for the procurement of API (Caffeine) with approval from DRAP Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision: The Board deferred the case for clarification of the above mentioned points.

57.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17866 dated 20-06-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 66410331823
	The proposed proprietary name / brand name	Panadol Migraine Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol……. 250mg Caffeine anhydrous….. 65mg Aspirin…… 250mg
	Pharmaceutical form of applied drug	Oral (Tablet)
	Pharmacotherapeutic Group of (API)	NSAID and Psychoactive drug.
	Reference to Finished product specifications	USP
	Proposed Pack size	**4 X6's**
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EXCEDRIN (MIGRAINE) by M/s GSK (GlaxosmithKline) Consumer Health, USA, Approved in USA. (OTC product)
	For generic drugs (me-too status)	….

	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conductd on 19-03-2019
	Name and address of API manufacturer.	**Paracetamol:** Citi Pharma Pvt Ltd 3.5-Km, Head Balloki Road, Phool Nagar Kasur- Pakistan. **Caffeine:** Aarti Industries Limited 1. Plot No D-53, phase II, M.I.D.C Kalyanshil RD Dombival (East) Thane 421204 Maharashtra state, India. 2. K-17/18/19, M.I.D.C, tararpur, Distict, Thane. **Aspirin:** JQC HUAYIN PHARMACEUTICAL CO., LTD. Yuqan Road,Huayian City, Shanxi Province. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of **Paracetamol, and** Caffeine is present in BP. The firm as submitted detail of nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Paracetamol:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (PGP14-37, PGP14-38, PGP14-39) **Caffeine:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (C-3011 C-3076, C-3115) **Aspirin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches: (A201104081, A201104082, A201104083
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Panadol Migraine Tablets by M/s GSK (GlaxosmithKline) Consumer Health, USA performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Panadol Migraine Tablets by M/s GSK (GlaxosmithKline)

		Consumer Health, USA in Acid media (pH-1.2),Acetate Buffer(pH-4.5) & Phosphate Buffer (pH 6.8).	
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API	Paracetamol: M/s Citi Pharma Private Limited Lahore. Caffeine: Aarti Industries Limited **Aspirin:** Jqc Huayin Pharmaceutical Co., Ltd.		
API Lot No.	**Caffeine:** **Paracetamol** : **Aspirin:** A201104081		
Description of Pack (Container closure system)	**PET plastic bottle**		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRA-PM001	TRA-PE002	TRA-PE003
Batch Size	10,000 Tablets	10,000 Tablets	10,000 Tablets
Manufacturing Date	**12-2021**	**12-2021**	**12-2021**
Date of Initiation	**09-2021**	**09-2021**	**09-2021**
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** Copy of cGMP certificate on the basis of evaluation conducted on 17-12-2020 and valid for 2 years **Caffeine**: Copy of GMP certificate No. NEW-WHO-GMP/KD/88375/2019/11/30185 issued by Food and Drug Administration Mahrashtra India-valid for 19-11-2022 **Aspirin:**	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Paracetamol:** Purchase documents Invoice No# F20-34 Dated: 11-08-2021 of Batch No # PGP21-513	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		
Remarks OF Evaluator: Firm submitted NOC as follows:			

M/s GlaxoSmithKline Consumer health Pakistan Limited 35-Dockyard Road, West Whraf –Karachi-Pakistan has provided no objection certificate for utilization of Panadol brand name as under :-

*"We, owners of the **"Panadol"** brand name since may decades globally and in Pakistan for last 45 years, would like to manufacture our following products at **"Citi Pharma Private Limited"** under the DRAP's Contract manufacturing policy:*

S.No.	***Brand Name***
1.	*Panadol Extra Tablets*
2.	*Panadol Migraine tablets*
3.	*Panadol Muscle Relaxant tablets*

*Further to this, Please note that we have no objection to the use of the brand Name **"Panadol"** for the aforementioned products, applied by Citi Pharma for the registration on contract manufacturing on behalf of GlaxoSmithKline consumer Healthcare Limited Pakistan.*

S.No	Section	Shortcomings Communicated
1.	1.6.5	• Submitted GMP certificate of different site than documents submitted for drug substance (Caffeine). • Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Aspirin manufacturer issued by relevant regulatory authority of country of origin.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active (Caffeine)Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) (Paracetamol and Caffeine and Aspirin)shall be submitted.
5.	3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / Active Pharmaceutical Ingredient (Paracetamol and Caffeine) manufacture.
6.	3.2.S.5	COA of primary / secondary reference standard including source and lot number for Caffeine and Aspirin shall be provided.
7.	3.2.P.1	• Composition of tablet is different from reference product in terms of excipients. • Applied formulation is film coated however it is not evident from composition in section 3.2.P.1 and 3.2.P.3.2 as there are no excipients for coating.
8.	3.2.P.2.3	Manufacturing process Coating step is not included however applied product is film coated.
9.	3.2.P.2.2.1	Submitted CDP data for paracetamol and Caffeine is same as in Panadol Extra tablet. Clarification s is required.
10.	3.2.P.3.5	Submitted Process validation protocol are general not product related. Clarification is required.
11.	3.2.P.5.1	Justify your acceptance criteria for dissolution test as NLT 75% after 60 minutes of the labeled amount of paracetamol ,caffeine and Aspirin while USP has specified as NLT 75% (Q) of the labelled amounts of acetaminophen , Aspirin and caffeine is dissolved
12.	3.2.P.5.3	Analytical Method Verification studies performed by the Drug Product manufacturer for drug product shall be submitted.
13.	3.2.P.6	COA of primary / secondary reference standard including source and lot number for paracetamol, Aspirin and Caffeine shall be provided
14.	3.2.P.8	• Manufacturing of batches was done in Dec, 2021 than how stability studies started in September 2021. • Stability studies of three (03) months submitted. • Documents for the procurement of API (Caffeine and Aspirin) with approval from DRAP

Decision: The Board deferred the case for clarification of above mentioned points.

Agenda of Evaluator PEC-XVIII (Mr. Muneeb Ahmed)

58.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilson's Pharmaceuticals Plot No. 387-388 Sector I-9. Industrial Area Islamabad.
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals Plot No. 387-388 Sector I-9. Industrial Area Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20198 dated 15.07.2022
	Details of fee submitted	PKR 75000/- dated 07.07.2022
	The proposed proprietary name / brand name	COLDENOL COLD + FLU SEVERE TABLET
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol….....325mg Dextromethorphan Hydrobromide….10mg Guaifenesin…….200mg Phenylephrine HCl….5mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Antipyretic/ Anti tussive/ Decongestant/ Expectorant
	Reference to Finished product specifications	As per Innovators Specifications
	Proposed Pack size	10's 20's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tylenol Cold Plus Flu Severe Caplets of Johnson & Johnson USA
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	Copy of inspection report by area FID dated 24.01.2018 indicates good level of GMP.
	Name and address of API manufacturer.	**Paracetamol:** M/s Saakh Pharma Pvt Limited, C-7/1, North Western Industrial zone Port Qasim Karachi. **Dextromethorphan Hydrobromide** M/s Oneiro Chemicals Pvt Limited, S. No. 475/P, at & Post Ekalbara Tal- Padra District Vadodara 391440 Gujarat India. **Guaifenesin** M/s Zhejiang Haizhou Pharmaceuticals Co., Ltd Linhai Industrial Zone, Linhai Zhejiang 317016 China. **Phenylephrine HCl** M/s Shenzhen Oriental Pharmaceutical Co., Ltd, 43 Dakeng Road, Tongle Village Longgang Town, Longgang District Guangdong China

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 3 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 3 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure (including dissolution testing) and batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the USFDA OTC Product Tylenol Cold Plus Flu Severe Tablets. CDP has been performed against the aforesaid brand in three media. The f2 value are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA	
Manufacturer of API	Paracetamol: M/s Saakh Pharma Pvt Limited, C-7/1, North Western Industrial Zone Port Qasim Karachi. Dextromethorphan Hydrobromide M/s Oneiro Chemicals Pvt Limited, S. No. 475/P, at & Post Ekalbara Tal- Padra District Vadodara 391440 Gujarat India. Guaifenesin M/s Zhejiang Haizhou Pharmaceuticals Co., Ltd Linhai Industrial Zone, Linhai Zhejiang 317016 China. Phenylephrine HCl M/s Shenzhen Oriental Pharmaceutical Co., Ltd, 43 Dakeng Road, Tongle Village Longgang Town, Longgang District Guangdong China
API Lot No.	Paracetamol: 19GN60219 Dextromethorphan Hydrobromide DX/L/017/018 Guaifenesin 18GF09667 Phenylephrine PEH-180101Y1
Description of Pack (Container closure system)	10's 20's & 30's Alu-Alu Blister Packing
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	325/10/200/5 Trial No. 1	325/10/200/5 Trial No. 1	325/10/200/5 Trial No. 1
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	02.03.2020	26.03.2020	26.03.2020
Date of Initiation	24.03.2020	17.04.2020	17.04.2020
No. of Batches	03		

Administrative Portion		
49.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided by the firm
50.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** GMP certificate issued by DRAP Karachi dated 23.06.2020. **Dextromethorphan Hydrobromide** Copy of DML issued by Commissioner Food & Drug Administration Gandhinagar India. **Guaifenesin** Copy of GMP certificate issued by CFDA China valid till 25.09.2023 **Phenylephrine** Copy of GMP certificate issued by Guangdong Food and Drug Administration China dated 12.09.2019
51.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided by the firm
52.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
53.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
54.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Evaluator:

The product (Tylenol Cold Plus Flu Severe Caplets of Johnson & Johnson USA) used for comparative dissolution is marketed as OTC (OTC Monograph Final) in USA. The label of the product contains a disclaimer which is as under:

***"DISCLAIMER:** Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies".*

Decision: Deferred for;

- **Evidence of approval of applied formulation as drug in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**
- **Submission of documents for the procurement of API with approval from DRAP (in case of import).**
- **Submission of Compliance Record of HPLC software 21CFR & audit trail reports on product testing.**

Agenda of Evaluator PEC-I

59.	Name, address of Applicant / Marketing Authorization Holder	M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Site: Petaro road Jamshoro, Pakistan.

		Office:35 Dockyard road, West Wharf Karachi.
	Name, address of Manufacturing site.	M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Site: Petaro road Jamshoro, Pakistan. Office:35 Dockyard road, West Wharf Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13217 dated 30/05/2022
	Details of fee submitted	PKR 75000/-: dated 16/02/2022
	The proposed proprietary name / brand name	Panadol Night Tablet 500mg/25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol……..…...500mg Diphenhydramine HCl…..25mg
	Pharmaceutical form of applied drug	Immediate release tablet
	Pharmacotherapeutic Group of (API)	Antipyretic, antihistamine
	Reference to Finished product specifications	In-House
	Proposed Pack size	2×10's
	Proposed unit price	Rs. 200 per pack
	The status in reference regulatory authorities	Panadol nightpain film coated tablet 500/25mg, MHRA Approved.
	For generic drugs (me-too status)	Could not be confirmed
	GMP status of the Finished product manufacturer	Copy of letter No. F.2-4/88-Lic(Vo-III) dated 27th January, 2022 whereby CLB in 284th meeting decided to grant renewal of DML.
	Section approval	Tablet General Section
	Name and address of API manufacturer.	Paracetamol: M/s Citi Pharma (pvt) ltd, 3.5-km, head balloki road, phool nagar Kasur. Diphenhydramine hydrochloride: M/s Recordati Industria Chimica & Farmaceutica SPA, via Mediana Cisterna, 4 04011-Compoverde di Aprilia (LT) Italy.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and

		its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Paracetamol:** • Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (PGP-14-37, PGP-14-38, PGP-14-39) **Diphenhydramine Hydrochloride:** • Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (13100167, 13100168, 13100170, 1410021316100565)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against Panadol Night Caplets mfg by Aspin Australia by performing all the quality tests. (B:DG111, DG112, DG113). CDP is submitted against Panadol Night Caplets mfg by Aspin Australia.
	Analytical method validation/verification of product	Analytical method verification/validation studies for drug product as well as for drug substance are submitted.

STABILITY STUDY DATA

Manufacturer of API	Paracetamol: M/s Citi Pharma (pvt) ltd, 3.5-km, head balloki road, phool nagar Kasur. Diphenhydramine hydrochloride: M/s Recordati Industria Chimica & Farmaceutica SPA, via Mediana Cisterna, 4 04011-Compoverde di Aprilia (LT) Italy.		
API Lot No.	PGP21-067 (Paracetamol) 20100520 (Diphenhydramine HCl)		
Description of Pack (Container closure system)	Blisters pack of 10 tablets of transparent PVC/PVDC film, heat sealed with hard tempered, lacquered Aluminium foil.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: Accelerated:		
Frequency	Accelerated: 0,1,3, 6, (month) Real Time: 0,1,3, 6, (month)		
Batch No.	4P4E	4P4F	4P4G
Batch Size	750,000 tabelts	750,000 tabelts	750,000 tabelts
Manufacturing Date	May, 2022	June, 2022	June, 2022
Date of Initiation	18/06/2021	18/06/2021	18/06/2021
No. of Batches	03		

Administrative Portion

8.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm

9.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Paracetamol: M/s Citi Pharma Copy of GMP certificate No. 112021-DRAP (FID-2036001-5101) dated 06/01/2021.. Diphenhydramine hydrochloride: Copy of GMP certificate No. IT-AP/28/H/2020 issuedon the basis of inspection conducted on 21/06/2019.
10.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of attested Invoice No. 6045000965 dated 21/10/2020. Copy of Form 6 dated 09/11/2020
11.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
13.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

<table>
<tr><th>Observations</th><th>Response</th></tr>
<tr><td>Valid copies of GMP certificates of manufacturers of drug substance (Paracetamol + Diphenhydramine HCl).</td><td>Paracetamol: M/s Citi Pharma
Copy of GMP certificate No. 112021-DRAP (FID-2036001-5101) dated 06/01/2021..
Diphenhydramine hydrochloride:
Copy of GMP certificate No. IT-AP/28/H/2020 issued on the basis of inspection conducted on 21/06/2019 AIFA Italy.</td></tr>
<tr><td>Provide analytical method verification studies including specificity, accuracy and precision for drug substances (Paracetamol & Diphenhydramine HCl) performed by drug product manufacturer.</td><td>The firm has submitted analytical method verification studies for the drug substances performed by drug product manufacturer.</td></tr>
<tr><td>Provide documents for the procurement of API with approval from DRAP for Diphenhydramine HCl.</td><td>Copy of attested Invoice No. 6045000965 dated 21/10/2020.
Copy of Form 6 dated 09/11/2020</td></tr>
<tr><td>Provide batch size for all three stability batch size term of number of tablets and date of initiation of stability studies.</td><td><table><tr><td>4P4E</td><td>4P4F</td><td>4P4G</td></tr><tr><td>750,000 tabs</td><td>750,000 tabs</td><td>750,000 tabs</td></tr><tr><td>May, 2022</td><td>June, 2022</td><td>June, 2022</td></tr><tr><td>18/06/2021</td><td>18/06/2021</td><td>18/06/2021</td></tr></table></td></tr>
<tr><td>Significant change is observed in the assay results of Diphenhydramine HCL in:
Accelerated stability studies for Batch Number 4P4E and 4P4G
Real time stability studies for Batch Number 4P4F
Please justify.</td><td>The assay results for Diphenhydramine HCI are dropped, however these are still well within shelf life specification i.e. 92.5-107.5%. The minimum assay value at 6 months accelerated condition is 94.80% and this justifies 2 year shelf life of the product.
The degradation profile of these batches were reviewed at 6 months accelerated conditions and notice no significant change in degradation products hence this justifies product stability over the shelf life.
The real time stability studies are continued and we have 9months & 12 months stability results which shows increased assay value for Diphenhydramine HCI. This indicates that drop observed at 3 & 6 months time point might be due to sample to sample and analytical variation and practically there is no significant change in assay of Diphenhydramine HCI. The results are tabulated below:</td></tr>
</table>

Batch Number	Initial results	Real Time 3 Months	% change	Real Time 6 Months	% change	Real Time 9 Months	% change	Real Time 12 Months	% change
4P4E	102.33%	94.13%	8.0 %	98.69%	3.5 %	101.70%	0.6 %	100.49%	1.7 %
4P4F	100.84%	97.89%	2.9 %	94.95%	5.8 %	100.40%	0.4 %	102.93%	2.0 %
4P4G	101.29%	96.45%	4.7 %	96.96%	4.2 %	100.40%	0.8 %	102.64%	1.3 %

Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

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

60.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma pvt ltd, 3km Head Balloki road Phool Nagar District Kasur.
	Name, address of Manufacturing site.	M/s Citi Pharma pvt ltd, 3km Head Balloki road Phool Nagar District Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15867 dated 20/06/2022
	Details of fee submitted	PKR 30,000/-: dated 16/04/2022
	The proposed proprietary name / brand name	Panadol Muscle Relaxant Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol……..…...650mg Orphenadrine Citrate…..50mg
	Pharmaceutical form of applied drug	Immediate release tablet
	Pharmacotherapeutic Group of (API)	NSAID, Skeletal muscle relexant
	Reference to Finished product specifications	In-House
	Proposed Pack size	3×5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Norgesic Tablets by M/s Inova Pty Limited, TGAAutralia
	For generic drugs (me-too status)	Nuberol forte by M/s Searle Paksitan ltd
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 158/2019-DRAP(AD-700521-1099) dated 13-06-2019 is submitted issued on the basis of inspection conducted on 19-03-2019.
	Section approval	Tablet General Section

	Name and address of API manufacturer.	Paracetamol: M/s Citi Pharma (pvt) ltd, 3.5-km, head balloki road, phool nagar Kasur. Orphenadrine Citrate: M/s Harika Drugs Private Limited, Kanukunta road, Gummadidala 502313 Medak District Andhra Pradesh India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Paracetamol:** • Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (PGP-14-37, PGP-14-38, PGP-14-39) **Orphenadrine Citrate:** • Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 12 months Batches: (HOCAPD005, HOCAPD006, HOCAPD007)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against Nuberol Forte by M/s Searle Pakistan ltd performing all the quality tests. (B:C0560). CDP is submitted against Nuberol Forte by M/s Searle Pakistan ltd. (B:10MPQVO) in all the three media that is 0.1NHCl, Acetate Buffer 4.5pH and Phosphate Buffer 6.8pH.
	Analytical method validation/verification of product	Analytical method verification/validation studies for drug product as well as for drug substance are submitted.

STABILITY STUDY DATA

Manufacturer of API	Paracetamol: M/s Citi Pharma (pvt) ltd, 3.5-km, head balloki road, phool nagar Kasur. Diphenhydramine hydrochloride: M/s Harika Drugs Private Limited, Kanukunta road, Gummadidala 502313 Medak District Andhra Pradesh India.
API Lot No.	(Paracetamol) HOCCPO024 (Orphenadrine citrate)
Description of Pack (Container closure system)	3×5's Blistered in Alu-PVC Packed in standard unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time:

	Accelerated:		
Frequency	Accelerated: 0,1,3, 6, (month) Real Time: 0,1,3, 6, (month)		
Batch No.	TRA-PMR001	TRA-PMR002	TRA-PMR003
Batch Size	10,000 tab	10,000 tab	10,000 tab
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation			
No. of Batches	03		

Administrative Portion

14.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
15.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Paracetamol: M/s Citi Pharma Copy of GMP certificate No. 10444/2016-DRAP(DDG) dated 18/07/2016. Orphenadrine Citrate:
16.	Documents for the procurement of API with approval from DRAP (in case of import).	
17.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
18.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
19.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Observations	**Response**
Valid copies of GMP certificates of manufacturers of drug substance (Paracetamol + Orphenadrine Citrate).	
Provide analytical method verification studies including specificity, accuracy and precision for drug substances (Paracetamol & Orphenadrine Citrate) performed by drug product manufacturer.	
Provide documents for the procurement of API with approval from DRAP for Orphenadrine Citrate.	
Justification is required for selection of dissolution parameter including type of apparatus, speed, medium (Phosphate buffer 5.8pH) and time (45mins-NLT75%(Q))	
Provide date of initiation of stability studies for all the three batches of the applied product.	
Clarification is required regarding the brand name of the applied product since you have provided two brand name that is Askprol CF Tablets and Panadol Muscle Relaxant Tablet.	
The submitted stability study data is till 3rd month time point. Please provide stability study data till 6th month time point for the applied product.	
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and	

accelerated) and Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	

Decision: The Board deferred the case for above mentioned points.

Agenda of Evaluator PEC-XV

61.	Name, address of Applicant / Marketing Authorization Holder	M/s Hiranis Pharmaceuticals (Pvt.) Ltd
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt.) Ltd Plot E-145-149, North western industrial zone, Port Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1099 dated 12/01/2022
	Details of fee submitted	PKR 75,000/-: dated 06/12/2021
	The proposed proprietary name / brand name	Parofen 150/500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ibuprofen 150mg + Paracetamol 500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Analgesics and antipyretics
	Reference to Finished product specifications	Manufacturer's Spec.
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA,TGA Australia Tachifene Tablet M/s Angelini Pharma Italian Medicine Agency approved.
	For generic drugs (me-too status)	Provas Duo Tablet 500/150 of M/s. Sami Pharmaceuticals, Karachi Reg.no.108837
	GMP status of the Finished product manufacturer	DML by way of formulation No. 000785 dated 03-02-2019

	Name and address of API manufacturer.	**Ibuprofen** M/s Hubei BiocauseHeilen Pharmaceutical Co., Ltd **Address:**122 Yangwan Road, Jingmen City, Hubei Province 448000, People's Republic of China **Paracetamol** M/s Zafa Chemie **Address**: Raiwind Manga Bypass, Near Sundar Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Ibuprofen:** Official monograph is present in United States pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Paracetamol:** Official monograph is present in British pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Ibuprofen:** **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches:** C100-1507197M, C100-1507198M & C100-1507199M **Paracetamol:** **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 54 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches:** 1331, 1332 & 1333
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Tachifene Tablet** by **M/s Angelini Francesco S.p.A (Lot no.021)** by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). CDP has been performed against the same brand that is **Tachifene Tablet by M/s Angelini Pharma** in Acid media (0.1 N HCL) & Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). For **Ibuprofen**: •It was found that both reference & test product shows low solubility in 0.1N HCl but resemblance in dissolution profile, the similarity factor, f2 is 93 which is greater than 50 & the difference factor f1 is 6 which is less than 15. •It was found that both reference & test product show low solubility in acetate Buffer pH 4.5 but resemblance in dissolution profile, the profile similarity factor, f2 is 93 which is greater than 50 & the difference factor f1 is 4 which is less than 15. •It was found that both reference & test product show greater than 85% dissolution within 15 minutes in Phosphate Buffer pH 6.8, therefore they are considered as similar & f2 value calculation is not applicable. For **Paracetamol**: • It was found that both reference & test product shows 85% dissolution within 15 minutes in 0.1N HCl shows resemblance in dissolution profile, the profile similarity factor, f_2 value calculation is not applicable. • It was found that both reference & test product shows greater than 85% dissolution within 15 minutes in acetate Buffer pH 4.5, therefore they are considered as similar & f_2 value calculation is not applicable. • It was found that both reference & test product show 85% dissolution within 15 minutes in Phosphate Buffer pH 6.8 shows resemblance in dissolution profile, therefore they are considered as similar & f_2 value calculation is not applicable.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	**Ibuprofen** M/s Hubei Biocause Heilen Pharmaceutical Co., Ltd **Address:**122 Yangwan Road, Jingmen City, Hubei Province 448000, People's Republic of China **Paracetamol** M/s Zafa Chemie **Address**: Raiwind Manga Bypass, Near Sundar Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore.
API Lot No.	**Ibuprofen** C100-1711278M **Paracetamol** 6019
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (3×10's)

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	**TF-020520**	**TF-030520**	**TF-040520**
Batch Size	1800 tablets	1800 tablets	1800 tablets
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	02-05-2020	04-05-2020	05-05-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Etoxib 90mg Tablet Etoxib 120mg Tablet Approved in 294th minutes of meeting of DRB
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ibuprofen:** Copy of GMP certificate No. HB20170363 issued by China Food and Drug Administration valid till 28/08/2022. **Paracetamol:** Copy of DML certificate No. 000589 issued by Drug Regulatory Authority of Pakistan valid till 02/10/2019*. (*Request for DML audit has already been submitted by M/s Zafa Chemie, DRAP against this letter has also instructed the concerned authority for conduct of timely audit of M/s Zafa Chemie via letter no. F.1-1/2006-Lic (Vol-II) dtd. 29-09-2021, copy of the same attached for reference in dossier).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Attested invoice from ADC attached for **Ibuprofen** Invoice No. W180316-035 Attested invoice from ADC attached for **Paracetamol**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	**Sections**	**Observations/Deficiencies/ Short-comings**
1.	**3.2.P.5.2**	Justify the dissolution parameter of applied drug product with reference to dissolution medium, acceptance criteria and other dissolution conditions, considering the USP general chapter <1092> and review report of innovator product.
2.	**3.2. P.8**	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Decision: Deferred for;

• **Justification of the dissolution parameter of applied drug product with reference to dissolution medium, acceptance criteria and other dissolution conditions, considering the USP general chapter <1092> and review report of innovator's product.** • **Provision of details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.**		
62.	Name, address of Applicant / Marketing Authorization Holder	M/s Hiranis Pharmaceuticals (Pvt.) Ltd
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt.) Ltd Plot E-145-149, North western industrial zone, Port Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.10870 dated 29/04/2022
	Details of fee submitted	PKR 75,000/- dated 21/04/2022
	The proposed proprietary name / brand name	Parofen Rapid Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ibuprofen 200mg + Paracetamol 500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Analgesics and antipyretics
	Reference to Finished product specifications	Manufacturer's Spec.
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nuromol Tablet M/s Reckitt Benckiser Pharma MHRA approved.
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	DML by way of formulation No. 000785 dated 03-02-2019
	Name and address of API manufacturer.	**Ibuprofen** M/s Hubei Biocause Heilen Pharmaceutical Co., Ltd **Address:**122 Yangwan Road, Jingmen City, Hubei Province 448000, People's Republic of China **Paracetamol** M/s Zafa Chemie **Address**: Raiwind Manga Bypass, Near Sundar Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and

		controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Ibuprofen:** Official monograph is present in United States pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Paracetamol:** Official monograph is present in British pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Ibuprofen:** **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 60 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches:** C100-1507197M, C100-1507198M & C100-1507199M **Paracetamol:** **Real time:** 30˚C ± 2˚C / 65% ± 5%RH for 54 months **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches:** 1331, 1332 & 1333
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Neuromol Tablet of M/s. Reckitt & Benckiser Sydney NSW, Australia** by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). CDP has been performed against the same brand that is **Neuromol Tablet of M/s. Reckitt & Benckiser Sydney NSW, Australia** in Acid media (0.1 N HCL) & Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). For **Ibuprofen**:

		•It was found that both reference & test product show low solubility in 0.1N HCl but resemblance in dissolution profile, the similarity factor, f2 is 93 which is greater than 50 & the difference factor f1 is 6 which is less than 15. •It was found that both reference & test product shows low solubility in acetate Buffer pH 4.5 but resemblance in dissolution profile, the profile similarity factor, f2 is 93 which is greater than 50 & the difference factor f1 is 4 which is less than 15. •It was found that both reference & test product shows greater than 85% dissolution within 15 minutes in Phosphate Buffer pH 6.8, therefore they are considered as similar & f2 value calculation is not applicable. For **Paracetamol**: • It was found that both reference & test product show 85% dissolution within 15 minutes in 0.1N HCl shows resemblance in dissolution profile, the profile similarity factor, f_2 value calculation is not applicable. • It was found that both reference & test product show greater than 85% dissolution within 15 minutes in acetate Buffer pH 4.5, therefore they are considered as similar & f_2 value calculation is not applicable. • It was found that both reference & test product show 85% dissolution within 15 minutes in Phosphate Buffer pH 6.8 shows resemblance in dissolution profile, therefore they are considered as similar & f_2 value calculation is not applicable.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**Ibuprofen** M/s Hubei Biocause Heilen Pharmaceutical Co., Ltd **Address:**122 Yangwan Road, Jingmen City, Hubei Province 448000, People's Republic of China **Paracetamol** M/s Zafa Chemie **Address**: Raiwind Manga Bypass, Near Sundar Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore.		
API Lot No.	**Ibuprofen** C100-1711278M **Paracetamol** 6019		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	**TF-050520**	**TF-060520**	**TF-080520**
Batch Size	1800 tablets	1800 tablets	1800 tablets
Manufacturing Date	05-2020	05-2020	05-2020

Date of Initiation	05-05-2020	06-05-2020	08-05-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Etoxib 90mg Tablet Etoxib 120mg Tablet Approved in 294th minutes of meeting of DRB
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ibuprofen:** Copy of GMP certificate No. HB20170363 issued by China Food and Drug Administration valid till 28/08/2022. **Paracetamol:** Copy of DML certificate No. 000589 issued by Drug Regulatory Authority of Pakistan valid till 02/10/2019*. (*Request for DML audit has already been submitted by M/s Zafa Chemie, DRAP against this letter has also instructed the concerned authority for conduct of timely audit of M/s Zafa Chemie via letter no. F.1-1/2006-Lic (Vol-II) dtd. 29-09-2021, copy of the same attached for reference in dossier).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Attested invoice from ADC attached for **Ibuprofen** Invoice No. W180316-035
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.P.5.2**	Justify the dissolution parameter of applied drug product with reference to dissolution medium, acceptance criteria and other dissolution conditions, considering the USP general chapter <1092> and review report of innovator product.
2.	**3.2. P.8**	Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.

Decision: Deferred for;

- **Justification of the dissolution parameter of applied drug product with reference to dissolution medium, acceptance criteria and other dissolution conditions, considering the USP general chapter <1092> and review report of innovator's product.**
- **Provision of details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.**

63.	Name, address of Applicant / Marketing Authorization Holder	Variant pharmaceuticals (Pvt.) Ltd.
	Name, address of Manufacturing site.	Plot # 5, M-2, Pharmazone, 26 km main Sharaqpur road district Sheikhupura.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23516 dated 19/08/2022
	Details of fee submitted	PKR 30,000/-: dated 23/06/2022
	The proposed proprietary name / brand name	Paracetamol 1000mg/100ml infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains Paracetamol ….10mg
	Pharmaceutical form of applied drug	Intravenous infusion
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ACETAMINOPHEN 1000mg/100ml infusion by **SANDOZ INC.** USFDA Approved.
	For generic drugs (me-too status)	BRAMOL 1000mg/100ml Infusion by M/s Brookes Pharma Private Ltd.., Reg. No. 089175
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020 General Tablet, General Capsule, General Sachet and General dry powder injectable (pre-lyophilized), General ampoule and vial section
	Name and address of API manufacturer.	Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol is present in USP/BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its

		verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Bofalgan** by M/s **Bosch Pharmaceuticals** Reg. No. 070607 by performing quality tests
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan		
API Lot No.	**00510941/044/2021**		
Description of Pack (Container closure system)	100ml glass Vial containing clear solution		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	18-11-2021	18-11-2021	18-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) issued by DRAP valid till 08-01-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.12192/2021/DRAP-AD-VIII(I&E) dated 12/08/2021 is submitted wherein the permission to import different APIs including Paracetamol for the purpose of test/analysis and stability studies is granted. Invoice # 322 date 03-09-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	**Sections**	**Observations/Deficiencies/ Short-comings**	**Reply of the Firm**
1.	**3.2. S.4.2**	Provide detailed analytical procedures used for the testing of drug substance by drug product manufacturer.	Firm submit the detailed analytical procedure used for testing of drug substance by drug product manufacturer.

2.	**3.2. S.4.3**	Provide analytical Method validation studies of drug substance performed by the drug product manufacturer.	Firm submit the analytical method verification report of drug substance performed by drug product manufacturer.
3.	**3.2. S.5**	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2. S.5.	Firm submitted the COA of working standard of M/s. Pharmagen Limited which was expired on 18th August,2021.
4.	**3.2.S.7**	COA of drug substance reveal that the injectable grade drug substance has been procured for the manufacturing of drug product, while the stability data of drug substance was of simple paracetamol, clarification is required in this regard.	Firm submitted the revised stability data of paracetamol injectable grade. However, the batch size of stability batches was of lab scale. As evident from batch title which are Lab experiment/001/2016,Lab experiment/002/2016,Lab experiment/003/2016,batch size has not mentioned on stability data summary sheets.
5.	**3.2. P.3.2**	Scientific justification is required for not using antioxidant in the applied formulation since the innovator brand used cysteine as an antioxidant because paracetamol is susceptible to degradation by oxidation.	Firm in their reply stated that We are using sodium metabisulphite that has anti-oxidant and preservative properties and it is compatible with our formulation as the product is stable under the real time and accelerated stability conditions.
6.	**3.2.P.5.4**	Assay has been performed on UV method as evident from the submitted analytical procedure and validation report, justify for choosing the UV method over HPLC method for assay in light of review reports of innovator and reference product.	Firm in their reply stated that, we have now upgraded the method from UV to HPLC the newly HPLC testing data of retain samples and stability samples is attached with this letter. Furthermore we have validated the testing method on HPLC and the data is attached.
7.	**3.2.P.5.4**	Scientific justification is required for not performing test of osmolality while batch release of trial batches of drug product, since the test has included in drug product specification of innovator brand.	The Osmolarity testing is now included in product testing specification the newly testing data of retain samples and stability samples is attached with this letter.

Decision: Approved.

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

Item No. 02 Registration applications of newly granted DML or New section (Human)

M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore

The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has approved the grant of DML by way of formulation for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general), notified vide letter no. F.1-10/2019-Lic. Dated 29-04-2022

64.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy. No 26378 dated 19-09-2022
	Details of fee submitted	Rs.30,000/- dated 13-09-2022
	The proposed proprietary name / brand name	**Inset 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains: Ondansetron as Hydrochloride dihydrate ……. 4mg
	Pharmaceutical form of applied drug	Clear and colorless solution filled in clear glass ampoules with blue color breaking ring
	Pharmacotherapeutic Group of (API)	Anti-emetics
	Reference to Finished product specifications	USP
	Proposed Pack size	4ml×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	ONSET Injection 4mg/2ml by M/s Pharmedic Laboratories (Pvt) Ltd.
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63 KSSIDC INDUSTRIAL ESTATE, Doddabullapur, banghaluru rural District-561203, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Onset injection by M/s Pharmedic.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63 KSSIDC INDUSTRIAL ESTATE, Doddabullapur, banghaluru rural District-561203, INDIA		
API Lot No.	AOND//20005		
Description of Pack (Container closure system)	Glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	03-2022	03-2022	03-2022
No. of Batches	03		

Observations	**Response**
Name of drug substance manufacturer is different from that mentioned in section 3.2.S.2.1.	It's a drafting error API Manufacturer is same as mentioned in 3.2.S.2.1.
Analytical method verification studies for drug substance shall be submitted from drug manufacturer.	Analytical method verification studies for drug substance Pharmaceutical is is performed submitted. by May & Baker Enclosed as Annex-\
Drug product specifications and analytical procedure shall be submitted.	USP monograph is adopted for drug product specifications and analytical procedure.
Documents confirming procurement of drug substance shall be submitted.	The material was borrowed from M/s Vision Pharmaceuticals for the trial batches.

Decision: Approved.

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

65.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy. No 26380 dated 19-09-2022
	Details of fee submitted	Rs.30,000/- dated 13-09-2022
	The proposed proprietary name / brand name	**Inset 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ondansetron as Hydrochloride dihydrate ……. 4mg
	Pharmaceutical form of applied drug	Clear and colorless solution filled in clear glass ampoules with blue color breaking ring
	Pharmacotherapeutic Group of (API)	Anti-emetics
	Reference to Finished product specifications	USP
	Proposed Pack size	2ml×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	ONSET Injection 4mg/2ml by M/s Pharmedic Laboratories (Pvt) Ltd.
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63 KSSIDC INDUSTRIAL ESTATE, Doddabullapur, banghaluru rural District-561203, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Onset injection by M/s Pharmedic.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63 KSSIDC INDUSTRIAL ESTATE, Doddabullapur, banghaluru rural District-561203, INDIA		
API Lot No.	AOND/RD/20005		
Description of Pack (Container closure system)	Glass ampoules		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	03-2022	03-2022	03-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. DCD/SPL.CL-1/CR-1510/2020-21) issued by Drugs Control Department Government of Karnataka India dated 06-02-2021. The GMP certificate is valid for one year from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

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

1.6.5	Name of Drug substance manufacturer is different form that mentioned in section 3.2.S.2.1	Firm has submitted that it was a drafting error and the drug substance manufacturer is same as mentioned in 3.2.S.2.1.
3.2. S.4.3	Analytical method verification studies for drug substance shall be submitted from drug product manufacturer.	Submitted.
3.2.P.5.1	Drug product specifications & analytical procedure shall be submitted.	Firm has referred to the USP monograph for "Ondansetron injection".
3.2.P.8	Documents confirming procurement of drug substance shall be submitted.	Firm has submitted "Loan Letter for API Ondansetron" from M/s Vision pharmaceuticals in the name of M/s M/s May & Baker

Decision: Approved.

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

66.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy. No 26377 dated 19-09-2022
	Details of fee submitted	Rs.30,000/- dated 13-09-2022
	The proposed proprietary name / brand name	**Co-min 500mcg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Mecobalamin USP …….500mcg
	Pharmaceutical form of applied drug	Liquid injectable
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Reference to Finished product specifications	--
	Proposed Pack size	1ml×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Methycobal Injection 0.5mg/ml by M/s Eisai Co, Ltd Tokyo, Japan, PMDA Japan Approved.
	For generic drugs (me-too status)	Biocobal injection 0.5mg/ml by M/s Surge Laboratories (Pvt) Ltd. Reg. No. 033385
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section

		(general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	Hebei Huarong Pharmacetical Co., Ltd. Address: East Road, North Circle, Shijiazhuang, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Medicobal injection by M/s Pharmedic.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	Hebei Huarong Pharmacetical Co., Ltd. Address: East Road, North Circle, Shijiazhuang, China		
API Lot No.	080302		
Description of Pack (Container closure system)	Glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate (Certificate#HE20180094) issued by Hebei Drug Administration, valid upto 18-11-2023 has been submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:

Section#	Observations	Firm's response
1.5.1	Submitted brand name mentions strength as 500mg/ml instead of 500mcg/ml.	It was a drafting error the mentioned strength is 500mcg/ml.
1.5.6	Pharmacopoeial reference for applied formulation has been declared as JP specifications whereas no JP monograph is available for applied formulation.	JP reference was intended for API & Finished drug product specifications as per innovator specifications.
3.2. S.4.1	Drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies Shall Be Submitted from M/s May & Baker.	JP monograph is adopted.
3.2.S.4.4	COA of relevant batch of API from drug substance manufacturer shall be submitted used for manufacturing of drug product trial batches.	Submitted.
3.2.P.5	Drug product specifications and analytical procedure shall be submitted.	Submitted.
3.2.P.5.4	Submitted COA declares average volume as 5ml. Justification shall be submitted in this regard.	Average volume is mentioned for 5 no. of units.
3.2.P.6	COA of reference/working standard shall be submitted.	Submitted.
3.2.P.8	• Complete batch manufacturing record of three stability batches shall be submitted. • Documents confirming procurement of drug substance shall be submitted.	• Submitted. • The material was borrowed from Global pharmaceuticals for trial batches.

Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

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

67.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy. No 26376 dated 19-09-2022
	Details of fee submitted	Rs.30,000/- dated 12-09-2022
	The proposed proprietary name / brand name	**V-Drop 5mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Vitamin D3 …….5mg
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	1ml(1x1,s)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**6** Approved by ANSM of France.
	For generic drugs (me-too status)	Indrop D Injection M/s Neutro Pharmaceutical Pvt Ltd Pakistan., Reg. No. 023170
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., Weichend Jinhe East Road, Shifang City, Sichuan Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.		
	Stability studies	Stability study conditions: Real time: 5˚C ± 3˚C Accelerated: 25˚C ± 2˚C / 60% ± 5%RH		
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Indrop D injection by M/s Neutro.		
	Analytical method validation/verification of product	Method validation studies have been submitted.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., Weichend Jinhe East Road, Shifang City, Sichuan Province, China.		
API Lot No.		VD3220513		
Description of Pack (Container closure system)		Glass ampoules		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 03 months Accelerated: 03 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		Trial 01	Trial 02	Trial 03
Batch Size		1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date		02-2022	02-2022	02-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML# SC 20160429 issued by NMPA valid till 18-10-2025.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2. S.4.1	Drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies Shall Be Submitted from M/s May & Baker.	
3.2.S.4.4	COA of relevant batch of API from drug substance manufacturer shall be submitted used for manufacturing of drug product trial batches.	
3.2.P.5.4	Submitted COA declares average volume as 5ml. Justification shall be submitted in this regard.	
3.2.P.6	COA of reference/working standard shall be submitted.	
3.2.P.8	• Complete batch manufacturing record of three stability batches shall be submitted. • GMP certificate of the drug substance manufacturer shall be submitted. • Documents confirming procurement of drug substance shall be submitted.	

Decision: The Board deferred the case for submission of;

- **Drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies Shall Be Submitted from M/s May & Baker.**
- **COA of relevant batch of API from drug substance manufacturer shall be submitted used for manufacturing of drug product trial batches.**
- **Submitted COA declares average volume as 5ml. Justification shall be submitted in this regard.**
- **COA of reference/working standard shall be submitted.**
- **Complete batch manufacturing record of three stability batches shall be submitted.**
- **GMP certificate of the drug substance manufacturer shall be submitted.**

Agenda of Evaluator PEC-XVI

68.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry

		powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy. No 26359 dated 19-09-2022
	Details of fee submitted	Rs.30,000/- dated 12-09-2022
	The proposed proprietary name / brand name	**WFI 5 ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml ampoule contains: Water for Injection …….5 ml
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Solvent/ Diluent
	Reference to Finished product specifications	USP/BP
	Proposed Pack size	1ml(1x1,s) (10's,14's,100's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	7 Approved by USFDA, MHRA, Sterile water **8** for Injection
	For generic drugs (me-too status)	WFI 5ml by Global Pharma
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	N/A
	Module-II (Quality Overall Summary)	Firm has submitted summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, batch analysis and justification of specification, and stability studies of drug product is submitted.
	Module III (Drug Substance)	Official monograph of sterile Water for injection is present in BP and USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for, specifications, analytical procedures, batch analysis and justification of specification.
	Stability studies	N/A
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical and batch analysis and justification of specification, container closure system and stability studies of drug product
	Pharmaceutical equivalence and comparative dissolution profile	Water for Injection Mfg By : Amros Phamrceuticals .
	Analytical method validation/verification of product	N/A

STABILITY STUDY DATA	
Manufacturer of API	N/A

API Lot No.	N/A		
Description of Pack (Container closure system)	BP type 1 ,Glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	N/A
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:

1. Firm has mentioned drug substance specification with acceptance criteria mentioning white or off-white, FTIR absorption, impurities and assay that does not corresponds to Claimed B.P & USP specifications., clarify.
2. Declared Pharmacopoeia specification in 1.5.6 are mentioned USP specification where in COA of Bulk water for injection mention BP. Clarify
3. Test for Total Organic Carbon is not mentioned in COA, same is required.
4. Container Closure mentioned as inner Packaging material: LDPE for medical packing, justification for this container closure is required.
5. The description of primary container is required along with justification.
6. Specification of bulk water testing does not mention Total Organic Carbon (TOC) and microbial testing.
7. Firm has mentioned sieving process through mechanical sifter under description of manufacturing process, which needs clarification and resubmission.
8. Under filling process, firm has mentioned “Dark green color vol. yellow color body injection containing off whit colour “Justification is required
9. The finished product specification is mentioned as BP whereas under 1.5.6 it is mentioned as USP, Clarification of applied specification of product is required
10. Complete testing specification of finished product is required including test for sub visible particle.
11. The declared B.P monograph is “sterilized water for injection” for finished drug product, whereas firm has adopted nomenclature 4for finish drug product as ‘water for injection’, therefore correction throughout module 2 & 3, (P part) is required
12. Firm has mentioned Inactive martial as Shell No.03, Which needs clarification.

	13. Required complete testing results conducted for stability studies data including PH/Alkalinity testing, Chloride, Ammonium, Calcium, Nitrate, sulphate, sub visible particles. TOC, conductivity test and, residue on evaporation for both real time and accelerated stability data for 6 months of trial batches.	
Decision: The Board deferred the case for the above mentioned points.		
69.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy. No 26360 dated 19-09-2022
	Details of fee submitted	Rs.30,000/- dated 12-09-2022
	The proposed proprietary name / brand name	**WFI 10 ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10 ml ampoule contains: Water for Injection …….10 ml
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Solvent/ Diluent
	Reference to Finished product specifications	USP/BP
	Proposed Pack size	1ml(1x1,s) (10's,14's,100's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	9 Approved by USFDA, MHRA, Sterile water **10** for Injection
	For generic drugs (me-too status)	Water for Injection of M/s Visison Pharma (Reg.# 032340)
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, batch analysis and justification of specification, and stability.studies of drug product is submitted.

	Module III (Drug Substance)	Official monograph of sterile Water for injection is present in BP and USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for, specifications, analytical procedures, batch analysis and justification of specification.
	Stability studies	N/A
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical and batch analysis and justification of specification, container closure system and stability studies of drug product
	Pharmaceutical equivalence and comparative dissolution profile	Water for Injection Mfg. By : Amros Pharmaceuticals .
	Analytical method validation/verification of product	N/A

STABILITY STUDY DATA

Manufacturer of API	N/A		
API Lot No.	N/A		
Description of Pack (Container closure system)	BP type 1 ,Glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	N/A
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted
Remarks of Evaluator:		

1. Firm has mentioned drug substance specification with acceptance criteria mentioning white or off-white, FTIR absorption, impurities and assay that does not corresponds to Claimed B.P & USP specifications., clarify. 2. Declared Pharmacopoeia specification in 1.5.6 are mentioned USP specification where in COA of Bulk water for injection mention BP. Clarify 3. Test for Total Organic Carbon is not mentioned in COA, same is required. 4. Container Closure mentioned as inner Packaging material: LDPE for medical packing, justification for this container closure is required. 5. The description of primary container is required along with justification. 6. Specification of bulk water testing does not mention Total Organic Carbon (TOC) and microbial testing. 7. The finished product specification is mentioned as BP whereas under 1.5.6 it is mentioned as USP, Clarification of applied specification of product is required 8. Complete testing specification of finished product is required including test for sub visible particle. 9. The declared B.P monograph is "sterilized water for injection" for finished drug product, whereas firm has adopted nomenclature for finish drug product as 'water for injection' , therefore correction throughout module 2 & 3, (P part) is required 10. Required complete testing results conducted for stability studies data including PH/Alkalinity testing, Chloride, Ammonium, Calcium, Nitrate, sulphate, sub visible particles. TOC, conductivity test and, residue on evaporation for both real time and accelerated stability data for 6 months of trial batches.
Decision: The Board deferred the case for the above mentioned points.

Agenda of Evaluator PEC-I

Cases of M/s Pinnacle Biotech (Pvt.) Ltd

M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi is granted New license on 13/09/2021 and has applied for the following products/molecules;

Number of molecules		**Number of products**
02		**03**
70.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25619 dated 12/09/2022
	Details of fee submitted	PKR 30,000/-: dated 17/08/2022
	The proposed proprietary name / brand name	Empaxo-M 12.5mg/ 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..….12.5mg Metformin HCl…….500mg
	Pharmaceutical form of applied drug	Blue, Oblong, Film Coated tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Antidiabetics, Biguanides, Antidiabetics, SGLT2 Inhibitors

	Reference to Finished product specifications	Innovator's
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY 12.5 /500mg Tablet by BOEHRINGER INGELHEIM PHARMACEUTICALS INC, USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met 12.5mg/500mg Tablet by Hilton Pharma (Pvt.) Ltd.,
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Section approval	Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved
	Name and address of API manufacturer.	**Empagliflozin** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin Hcl.** M/s. Exemed Pharmaceuticals Co. Ltd. Block No. 628 (A & B) ECP Canal Road, Vill : Luna, Taluka: Padra, District: Vadodara – 391440, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Empagliflozin.** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04 **Metformin HCl** Firm has submitted signed and stamped stability data sheets as per zone IV-B in which real time stability data conditions are: Real time: 30˚C ± 2˚C / 75% ± 5%RH 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: MFH11001AFP, MFH11002AFP, MFH11003AFP
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence studies with reference product i.e., Xenglu-Met 12.5mg- 500mg Tablet whereby all the quality tests have been performed. CDP is submitted against the same brand and f2 values are in the acceptable range.		
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.		
STABILITY STUDY DATA				
Manufacturer of API		**Empagliflozin** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin Hcl.** M/s. Exemed Pharmaceuticals Co. Ltd. Block No. 628 (A & B) ECP Canal Road, Vill : Luna, Taluka: Padra, District: Vadodara – 391440, Gujarat, India		
API Lot No.		Empagliflozin H-E-20210605-D01-E06-02 Metformin HCl MFH211237AFP		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5% Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		22TTEMM001	22TTEMM002	22TTEMM003
Batch Size		1500 tab	1500 tab	1500 tab
Manufacturing Date		02-2022	03-2022	03-2022
Date of Initiation		16-03-2022	16-03-2022	16-03-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: Copy of GMP certificate No. LN210011 dated26/05/2021 issued by Lioning Drug Administration. Metformin: Copy of GMP certificate No. 21082838 dated 07/08/2021 valid till 06/08/2024 issued by Food and Drugs Control Adminsitrtaion Gujarat India.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin : Copy of Form 6 No. 942 dated 10/12/2021 and Copy of attested invoice No. HN20211027-A dated 30/11/2021.		

		Metformin: Copy of attested invoice no. GSTVAD2122427 dated 23/11/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Observations	**Response**
Valid copies of GMP certificates of manufacturers of drug substance (Empaglilozin+Metformin HCl).	Empagliflozin: Copy of GMP certificate No. LN210011 dated26/05/2021 issued by Lioning Drug Administration. Metformin: Copy of GMP certificate No. 21082838 dated 07/08/2021 valid till 06/08/2024 issued by Food and Drugs Control Adminsitrtaion Gujarat India.
Provide analytical method verification studies including specificity, accuracy and precision for drug substances (Empaglilozin+Metformin HCl) performed by drug product manufacturer.	The firm has submitted analytical method verification studies for stiagliptin and Metformin including accuracy, specificity and precision (inter day and Intra day).
Provide documents (invoice etc) for the procurement of API with approval from DRAP for Empgliflozin and Metformin HCl	Empagliflozin : Copy of Form 6 No. 942 dated 10/12/2021 and Copy of attested invoice No. HN20211027-A dated 30/11/2021. Metformin: Copy of attested invoice no. GSTVAD2122427 dated 23/11/2021.
Please provide pharmaceutical equivalence data and CDP for the applied product along with the details of the reference/innovator's product (Batch Number, expiry, manufacturing date etc) against which the said studies have been performed.	Pharmaceutical equivalence studies with reference product i.e., Xenglu-Met 12.5mg-500mg Tablet whereby all the quality tests have been performed. CDP is submitted against the same brand and f2 values are in the acceptable range.
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) and Compliance Record of HPLC software 21CFR & audit trail reports on product testing (soft copy).	Submitted.

Decision: Approved.

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

Agenda of Evaluator PEC-XV

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

	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25621 dated 12/09/2022
	Details of fee submitted	PKR 30,000/-: dated 17/08/2022
	The proposed proprietary name / brand name	Sitamax-M 50mg + 500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sitagliptin as Phosphate Monohydrate……50mg Metformin Hydrochloride……..500mg
	Pharmaceutical form of applied drug	light brown color, oblong shape film coated tablet plain on both sides.
	Pharmacotherapeutic Group of (API)	Antidiabetics, Biguanides / Dipeptidyl Peptidase-IV Inhibitors.
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JANUMET Tablets 50mg/500mg, MERCK SHARP AND DOHME CORP, FDA
	For generic drugs (me-too status)	Treviamet by Getz Pharma Pakistan (Pvt.) Ltd. Reg No: 055443
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Section approval	Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved
	Name and address of API manufacturer.	**Sitagliptin Phosphate Monohydrate** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl** M/s. Exemed Pharmaceuticals Co. Ltd. Block No. 628 (A & B) ECP Canal Road, Vill : Luna, Taluka: Padra, District: Vadodara – 391440, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Empagliflozin.** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04 **Metformin HCl** Firm has submitted signed and stamped stability data sheets as per zone IV-B in which real time stability data conditions are: Real time: 30˚C ± 2˚C / 75% ± 5%RH 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: MFH11001AFP, MFH11002AFP, MFH11003AFP
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is JANUMET 50/ 500mg Tablets by MERCK SHARP AND DOHME CORP., performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is JANUMET 50/ 500mg Tablets by MERCK SHARP AND DOHME CORP., in Acid media (pH 0.1-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.
STABILITY STUDY DATA		
Manufacturer of API		**Sitagliptin** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin Hcl.** M/s. Exemed Pharmaceuticals Co. Ltd. Block No. 628 (A & B) ECP Canal Road, Vill : Luna, Taluka: Padra, District: Vadodara – 391440, Gujarat, India

API Lot No.	Sitagliptin H-GWC-20210617-D04-GWCO4-06 Metformin HCl MFH211237AFP		
Description of Pack (Container closure system)	Alu-Alu Blister Strip of 2x7's Tablets Packed in a Printed Unit Carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22TTSIM007	22TTSIM008	22TTSIM009
Batch Size	1500 Tab	1500 Tab	1500 Tab
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	16-03-2022	16-03-2022	16-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sitagliptin: Copy of GMP certificate No. LN210011 dated26/05/2021 issued by Lioning Drug Administration. Metformin: Copy of GMP certificate No. 21082838 dated 07/08/2021 valid till 06/08/2024 issued by Food and Drugs Control Adminsitrtaion Gujarat India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Sitagliptin: Copy of attested invoice No. HN20211027-A dated 30/11/2021. Metformin: Copy of attested invoice no. GSTVAD2122427 dated 23/11/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Observations	**Response**
Valid copies of GMP certificates of manufacturers of drug substance (Sitagliptin+Metformin HCl).	Sitagliptin: Copy of GMP certificate No. LN210011 dated26/05/2021 issued by Lioning Drug Administration. Metformin: Copy of GMP certificate No. 21082838 dated 07/08/2021 valid till 06/08/2024 issued by Food and Drugs Control Adminsitrtaion Gujarat India.

Provide analytical method verification studies including specificity, accuracy and precision for drug substances (Sitagliptin+Metformin HCl) performed by drug product manufacturer.	The firm has submitted analytical method verification studies for stiagliptin and Metformin including accuracy, specificity and precision (inter day and Intra day).
Provide documents (invoice etc) for the procurement of API with approval from DRAP for Sitagliptin and Metformin HCl	Sitagliptin: Copy of attested invoice No. HN20211027-A dated 30/11/2021. Metformin: Copy of attested invoice no. GSTVAD2122427 dated 23/11/2021.
Please provide pharmaceutical equivalence data and CDP for the applied product along with the details of the reference/innovator's product (Batch Number, expiry, manufacturing date etc) against which the said studies have been performed.	Pharmaceutical Equivalence have been established against the brand leader that is JANUMET 50/ 500mg Tablets by MERCK SHARP AND DOHME CORP., performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is JANUMET 50/ 500mg Tablets by MERCK SHARP AND DOHME CORP., in Acid media (pH 0.1-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) and Compliance Record of HPLC software 21CFR & audit trail reports on product testing (soft copy).	Submitted.

Decision: Approved.

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

72.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25622 dated 12/09/2022
	Details of fee submitted	PKR 30,000/-: dated 17/08/2022
	The proposed proprietary name / brand name	Sitamax-M 50mg + 1000mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sitagliptin as Phosphate Monohydrate……50mg Metformin Hydrochloride……..1000mg
	Pharmaceutical form of applied drug	light brown color, oblong shape film coated tablet plain on both sides.

	Pharmacotherapeutic Group of (API)	Antidiabetics, Biguanides / Dipeptidyl Peptidase-IV Inhibitors.
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Janumet Tablets 50mg/1000mg by M/s Merck Sharp and Dohme Corp, USFDA Approved.
	For generic drugs (me-too status)	Treviamet 50mg/1000mg Tablet by M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 055444
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Section approval	Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved
	Name and address of API manufacturer.	**Sitagliptin Phosphate Monohydrate** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl** M/s. Exemed Pharmaceuticals Co. Ltd. Block No. 628 (A & B) ECP Canal Road, Vill : Luna, Taluka: Padra, District: Vadodara – 391440, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Sitagliptin** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: M-20191010-D05-M06-02, M-20191010-D05-M06-03, M-20191010-D05-M06-04 **Metformin HCl** Firm has submitted signed and stamped stability data sheets as per zone IV-B in which real time stability data conditions are:

		Real time: 30°C ± 2°C / 75% ± 5%RH 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH 6 months Batches: MFH11001AFP, MFH11002AFP, MFH11003AFP
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Janumet Tablets 50mg/1000mg by M/s Merck Sharp and Dohme Corp, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Janumet Tablets 50mg/1000mg by M/s Merck Sharp and Dohme Corp, Pharma in Acid media (pH 0.1-1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.

STABILITY STUDY DATA

Manufacturer of API	**Sitagliptin** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin Hcl.** M/s. Exemed Pharmaceuticals Co. Ltd. Block No. 628 (A & B) ECP Canal Road, Vill : Luna, Taluka: Padra, District: Vadodara – 391440, Gujarat, India		
API Lot No.	Sitagliptin H-GWC-20210617-D04-GWCO4-06 Metformin HCl MFH211237AFP		
Description of Pack (Container closure system)	Alu-Alu Blister Strip of 2x7's Tablets Packed in a Printed Unit Carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22TTSIM001	22TTSIM002	22TTSIM003
Batch Size	1500 Tab	1500 Tab	1500 Tab
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	16-03-2022	16-03-2022	16-03-2022
No. of Batches	03		

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm

8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sitagliptin: Copy of GMP certificate No. LN210011 dated26/05/2021 issued by Lioning Drug Administration. Metformin: Copy of GMP certificate No. 21082838 dated 07/08/2021 valid till 06/08/2024 issued by Food and Drugs Control Adminsitrtaion Gujarat India.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Sitagliptin: Copy of attested invoice No. HN20211027-A dated 30/11/2021. Metformin: Copy of attested invoice no. GSTVAD2122427 dated 23/11/2021.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Observations	**Response**
Valid copies of GMP certificates of manufacturers of drug substance (Sitagliptin+Metformin HCl).	Sitagliptin: Copy of GMP certificate No. LN210011 dated26/05/2021 issued by Lioning Drug Administration.. Metformin: Copy of GMP certificate No. 21082838 dated 07/08/2021 valid till 06/08/2024 issued by Food and Drugs Control Adminsitrtaion Gujarat India.
Provide analytical method verification studies including specificity, accuracy and precision for drug substances (Sitagliptin+Metformin HCl) performed by drug product manufacturer.	The firm has submitted analytical method verification studies for stiagliptin and Metformin including accuracy, specificity and precision (inter day and Intra day).
Provide documents (invoice etc) for the procurement of API with approval from DRAP for Sitagliptin and Metformin HCl	Sitagliptin: Copy of attested invoice No. HN20211027-A dated 30/11/2021. Metformin: Copy of attested invoice no. GSTVAD2122427 dated 23/11/2021.
Please provide pharmaceutical equivalence data and CDP for the applied product along with the details of the reference/innovator's product (Batch Number, expiry, manufacturing date etc) against which the said studies have been performed.	Pharmaceutical Equivalence have been established against the brand leader that is JANUMET 50/ 500mg Tablets by MERCK SHARP AND DOHME CORP., performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is JANUMET 50/ 500mg Tablets by MERCK SHARP AND DOHME CORP., in Acid media (pH 0.1-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) and Compliance Record of HPLC software 21CFR & audit trail reports on product testing (soft copy).	Submitted.

Decision: Approved.

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

commitment submitted in the registration application.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Miscellaneous Cases:

M/s NABIQASIM submitted a letter on subject "Registration of Glem-Lin Tablets on Out-of-Que Basis in Light of Decision made in Authority Meeting dated 15th September 2022" which is reproduced as under:

This has reference to the aforementioned subject and decision made in the last Authority Meeting dated 15th September 2022, to ensure continuous supply of Paracetamol Tablets and to incentivize manufacturer thereon in form of out-of-queue consideration of application of 1 generic (Me-too) molecule on manufacturing and immediate distribution of atleast 15,000 packs of Paracetamol Tablets with pack size of 200 Tablets.

We in this regard, would like to inform that in light of the aforementioned decision of Authority we immediately started the manufacturing of our Registered Product Reliefal 500mg Tablets (Paracetamol) having Registration No. 002728 with pack size of 200s and we have supplied 15,000 packs to our Authorized Distributors across Pakistan (Details of stock dispatched and receiving thereon on delivery challan enclosed herewith).

In this regard, we would like to request you to kindly include our applied branded generic Empagliflozin + Metformin Tablets in the agenda of 321st DRB Meeting, for registration on out-of-queue basis, under the aforementioned Authority decision.

The firm has submitted copies of delivery challans in respect of its distributor mentioning 15,000 packs (pack size 200 tablets) dated 19-09-2022

Further details of aforementioned molecule (Me-too) are given below:

S.No	Proposed Brand Name	Composition	Pack Size	Date of Dossier Submission
1	GLEM-LIN TABLETS 10mg/5mg	Each film coated tablet contains: Empagliflozin……10mg Linagliptim……. 5mg	14's 28's	21-07-2022
2	GLEM-LIN TABLETS 25mg/5mg	Each film coated tablet contains: Empagliflozin……25mg Linagliptim……. 5mg	14's 28's	21-07-2022

73.	Name, address of Applicant / Marketing Authorization Holder	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Name, address of Manufacturing site.	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20634 dated 21/07/2022
	Details of fee submitted	PKR 30,000/-: dated 06/07/2022
	The proposed proprietary name / brand name	GLEM-LIN tablet 10mg/5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin …. 10mg Linagliptin …….. 5mg
	Pharmaceutical form of applied drug	White colored, round shaped, film coated tablet, both sides plain
	Pharmacotherapeutic Group of (API)	First in class dual inhibitor combination therapy (SGLT2/DPP-4) Type 2 Diabetes Mellitus, antidiabetic agent
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	14's & 28's tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product GLYXAMBI 10mg+5mg film-coated tablets (Empagliflozin 10mg + Linagliptin 5mg) is Manufactured for: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 USA and Eli Lilly and Company, Indianapolis, IN 46285 USA).
	For generic drugs (me-too status)	**Getz Pharma**. **Diampa LT tablet** 10mg/5mg (Reg. No. 112552) Empagliflozin 10mg + Linagliptin 5mg Pack size: 14's
	GMP status of the Finished product manufacturer	GMP Certificate dated 19/09/2020. Tablet (General & Antibiotic)
	Name and address of API manufacturer.	**<u>Empagliflozin</u>** **Zhejiang Hongyuan Pharmaceuticals. Co.** Chem & API's Industrial Zone, Linhai, Zhejiang Province, China **<u>Linagliptin</u>** **Anhui Haikang Pharmaceutical Co., Ltd.** Add:No. 21 Huancheng West road, Anqing Anhui Provine 246000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification/validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**<u>Empagliflozin</u>** Monograph of Empagliflozin is present is as per In-house (Manufacturer's) specifications. The firm as submitted detail of nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Impurity A, Impurity C, Any single impurity, Total impurities, Heavy metal, Chiral purity R-isomer), Residual solvent (Dichloromethane, Ethanol, Methanol, Ethyl acetate, Tetrahydrofuran, Toluene), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **<u>Linagliptin</u>** Monograph of Linagliptin is present is as per In-house (Manufacturer's) specifications. The firm as submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Single Impurity, Total impurity), residual solvent (Isopropanol, Dichloromethane, N, N-Dimethylacetamide), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Empagliflozin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (Z1215-170601, Z1215-170602, Z1215-170603) **Linagliptin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 4 Years Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20150901, 20150902, 20150903)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Glyxambi Tablet 10mg/5mg tablet (Empagliflozin 10mg+ Linagliptin 5mg) is registered and being marketed by Boehringer Ingelheim Pharmaceuticals, Inc. by performing quality tests (Description, Disintegration, Identification, Dissolution and Assay). CDP has been performed against the same brand that is Glyxambi Tablet 10mg/5mg tablet (Empagliflozin 10mg+ Linagliptin 5mg) by Boehringer Ingelheim Pharmaceuticals, Inc., in Acid media (pH 1.2) & Phosphate Buffer (pH 4.5, 5.5 & 6.8).
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**<u>Empagliflozin</u>** **Zhejiang Hongyuan Pharmaceuticals. Co.** Chem & API's Industrial Zone, Linhai, Zhejiang Province, China Tel: 86-571-88278597 Fax: 66-571-88278590 **<u>Linagliptin</u>** **Anhui Haikang Pharmaceutical Co., Ltd.** Add:No. 21 Huancheng West road, Anqing Anhui Provine 246000, China		
API Lot No.	**<u>Empagliflozin</u>** EPG20211101 **<u>Linagliptin</u>** 21102401		
Description of Pack (Container closure system)	Alu-Alu blister 14's & 28's tablets packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6(Months)		
Batch No.	525DS01	525DS02	525DS03
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	23-02-2022	23-02-2022	23-02-2022
No. of Batches	03		

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate no ZJ20180032 issued by Food and Drug Administration, China valid till 14/03/2023.

		Linagliptin: Copy of DML certificate no. 20190399 issued by Anhui Provincial Drug Administration valid till 31/12/2025.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Copy of invoice no HHSC-211025-1 dated 08-12-2021 duly attested by Assistant Director, DRAP, Karachi on 24-12-2021 was provide. **Linagliptin:** Copy of CI No. WD202105073 dated 29-10-2021 duly attested by Assistant Director, DRAP, Karachi on 12-11-2021 was provide.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Linagliptin:
Submitted Drug Manufacturing License of linagliptin access online dated 22-09-2022 from NMPA China official website which shows that:
production range (copy)
ganciclovir, valganciclovir hydrochloride, imatinib mesylate, repaglinide, sitagliptin phosphate, vipaglitin, cerrodoxine

Empagliflozin:
Submitted Drug Manufacturing License of Empagliflozin access online dated 22-09-2022 from NMPA China official website which shows that:
production range (copy)
atorvastatin calcium, azisartan

Decision: Approved.

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

73.	Name, address of Applicant / Marketing Authorization Holder	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20633, dated 21-07-2022
	Details of fee submitted	PKR 30,000/-, dated 06-07-2022
	The proposed proprietary name / brand name	GLEM-LIN 25mg/5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……. 25mg Linagliptin ……..... 5mg
	Pharmaceutical form of applied drug	Pink colored, round shaped, film coated tablet, both sides plain
	Pharmacotherapeutic Group of (API)	First in class dual inhibitor combination therapy (SGLT2/DPP-4) Type 2 Diabetes Mellitus, antidiabetic agent
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's, 28's, Packed in Alu Alu Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	GLYXAMBI 25mg+5mg film-coated tablets (Empagliflozin 25mg + Linagliptin 5mg) USFDA approved.
	For generic drugs (me-too status)	Diampa LT Tablet 25mg/5mg (Reg.No.112532) by Getz Pharma.
	GMP status of the Finished product manufacturer	GMP Certificate issued based upon evaluation conducted on 19-09-2020.
	Name and address of API manufacturer.	**Empagliflozin** Zhejiang Hongyuan Pharmaceuticals. Co. Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China **Linagliptin** **Anhui Haikang Pharmaceutical Co., Ltd.** Add:No. 21 Huancheng West road, Anqing Anhui Provine 246000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification / validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin** Monograph of Empagliflozin is present is as per In-house (Manufacturer's) specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Impurity A, Impurity C, Any single impurity, Total impurities, Heavy metal,

		Chiral purity R-isomer), Residual solvent (Dichloromethane, Ethanol, Methanol, Ethyl acetate, Tetrahydrofuran, Toluene), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **<u>Linagliptin</u>** Monograph of Linagliptin is present is as per In-house (Manufacturer's) specifications. The firm as submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Single Impurity, Total impurity), residual solvent (Isopropanol, Dichloromethane, N, N-Dimethylacetamide), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Empagliflozin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (Z1215-170601, Z1215-170602, Z1215-170603) **Linagliptin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 4 Years Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20150901, 20150902, 20150903)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Glyxambi Tablet 25mg/5mg tablet (Empagliflozin 25mg+ Linagliptin 5mg) batch No. 21H223 is registered and being marketed by Boehringer Ingelheim Pharmaceuticals, Inc. by performing quality tests (Description, Disintegration, Identification, Dissolution and Assay). CDP has been performed against the same brand that is Glyxambi Tablet 25mg/5mg tablet (Empagliflozin 25mg+ Linagliptin 5mg) by Boehringer Ingelheim Pharmaceuticals, Inc., in

		Acid media (pH 1.2) & Phosphate Buffer (pH 4.5, 5.5 & 6.8).		
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		**Empagliflozin** Zhejiang Hongyuan Pharmaceuticals. Co. Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China **Linagliptin** Anhui Haikang Pharmaceutical Co., Ltd. Add:No. 21 Huancheng West road, Anqing Anhui Provine 246000, China		
API Lot No.		**Empagliflozin** EPG20211101 **Linagliptin** 21102401		
Description of Pack (Container closure system)		Alu-Alu blister 14's & 28's Tablets packed in unit carton.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		526DS01	526DS02	526DS03
Batch Size		5000 tablets	5000 tablets	5000 tablets
Manufacturing Date		02-2022	02-2022	02-2022
Date of Initiation		24-02-2022	24-02-2022	24-02-2022
No. of Batches		03		
Administrative Portion				
13.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.		
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate no ZJ20180032 issued by Food and Drug Administration, China valid till 14/03/2023. Submitted GMP is not of relevant product (Atorvastatin) **Linagliptin:** Copy of DML certificate no. 20190399 issued by Anhui Provincial Drug Administration valid till 31/12/2025. This shows that production range (copy) ganciclovir, valganciclovir hydrochloride, imatinib mesylate, repaglinide, sitagliptin phosphate, vipaglitin, cerrodoxine		
15.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Copy of invoice no HHSC-211025-1 dated 08-12-2021 duly attested by Assistant Director, DRAP, Karachi on 24-12-2021 was provide. **Linagliptin:**		

		Copy of CI No. WD202105073 dated 29-10-2021 duly attested by Assistant Director, DRAP, Karachi on 12-11-2021 was provide.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Linagliptin:

Submitted Drug Manufacturing License of linagliptin access online dated 22-09-2022 from NMPA China official website which shows that: production range (copy) ganciclovir, valganciclovir hydrochloride, imatinib mesylate, repaglinide, sitagliptin phosphate, vipaglitin, cerrodoxine

Empagliflozin:

Submitted Drug Manufacturing License of Empagliflozin access online dated 22-09-2022 from NMPA China official website which shows that:

production range (copy)

atorvastatin calcium, azisartan

Decision: Approved.

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

ADDITIONAL AGENDA

A. Imported Enoxaparin & Heparin Injections deferred in 320th Registration Board meeting.

1.	**Name, address of Applicant / Importer**	**M/s Calory Pharma,** **75-B, Circular Street No. 13, Central Lane, Phase-II, DHA, Karachi.**
	Details of Drug Sale License of importer	**License No:** 110 **Address:** 75-B, Circular Street No. 13, Central Lane, Phase-II, DHA, Karachi. **Validity: 06-07-2023** **Status:** License to sell drugs by way of whole sale.
	Name and address of marketing authorization holder (abroad)	M/s Biem Ilac San. Ve Tic. A.S, Turgut Reis Cad. No.: 21 06570 Tandogan/ Ankara, Turkey.
	Name, address of manufacturer(s)	M/s Mefar Ilac San. A.S., Ramazanoglu Mah. Ensar Cad No: 20 Kurtkoy-Pendik/ Istanbul, Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• Firm has submitted legalized CoPP (No. 2021/1843) dated 10-06-2021 valid till 10-06-2023 issued by Turkish Medicines & Medical Devices Agency. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of the product in country of origin.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific Letter of Authorization from General Manager of M/s Biem Ilac Sanayi ve Ticaret A.S. According to the letter, the firm *M/s Biem Ilac* authorizes "Calory Pharma" to promote, market, sell and perform the registration procedures for the product. The letter was issued on 01-12-2021.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3272 (R&I) Dated 03-02-2022
	Details of fee submitted	Rs. 150,000/- dated 04-01-2022
	The proposed proprietary name / brand name	**Biemparin**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Heparin Sodium……5000IU
	Dosage form of applied drug	Injection

	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's Vial (5mL)
	Proposed unit price	As per SRO/DPC
	Shelf Life	02 Years
	Storage Conditions	$\leq 30^0$C
	The status in reference regulatory authorities	Heparin Panpharma of M/s Panpharma, France.
	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Module-II (Quality Overall Summary)	Firm has submitted ICH QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Yino Pharma Ltd., 2 Cuiping Erxiang, Yubei District, Chongqing, 401120, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Drug Substance at real time conditions for 18 months. The real time stability data conducted at 25^0C$\pm 2^0$C/60±5%RH is for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted validation of Analytical methods of Heparin Sodium Assay, benzyl Alcohol determination.
	Container closure system of the drug product	5mL Type I Colorless Glass vial, 20 mm gray brombutyl stopper, 20 mm blue flip-of cover.
	Stability study data of drug product	Firm has submitted stability study data of one commercial process validation batch. The accelerated stability study data is conducted at 40 ± 2^0C/75%RH±5% for 6 months. The real time stability study data is conducted at 25 ± 2^oC/60%±5RH for 24 months.
	Remarks of Evaluator	• pH specification limits are different in Finished product specifications (5.5 to 7.0), in stability studies (5.0 to 7.5) and in European Pharmacopoeia (5.5 to 8.0) • Benzyl Alcohol specification limits are different in Finished product specifications (90% to 110%) and in stability studies (80% to 110%)

		• The firm has submitted stability study data of only one commercial Process Validation batch. • Non- clinical and Clinical trial data are not submitted by the firm. Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product, hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin.
	Previous Decision(M-320)	*Registration Board deferred the case for submission of following by the firm:* *i. Clarification of different pH specification limits in Finished product specifications (5.5 to 7.0), in stability studies (5.0 to 7.5) and in European Pharmacopoeia (5.5 to 8.0)* *ii. Clarification of different Benzyl Alcohol specification limits in Finished product specifications (90% to 110%) and in stability studies (80% to 110%).* **iii.** *Real time & Accelerated Stability study data of three commercial batches.*

Evaluation by DBE&R:

Now the firm has submitted following response which is summarized in below table against each query:

Queries	Response
Clarification of different pH specification limits in Finished product specifications (5.5 to 7.0), in stability studies (5.0 to 7.5) and in European Pharmacopoeia (5.5 to 8.0)	*we would like to explain regarding your query for pH limit variations. Accordingly, we explain that in the stability studies data, the limit is shelf-life limit. It is determined according to Heparin Injection finished product monograph. The limit in the USP monograph is used as the shelf-life limit. The limit in the EP monograph is for API. Release limit of pH is 5.5 -7.0 and it is tighter than both USP and EP monographs. Therefore, there will be no risk to the quality of the finished product. For your review, the USP monograph is in attachment.* *We kindly request that our relevant cover letter and its attachments can be taken into your records and evaluated.*
Clarification of different Benzyl Alcohol specification limits in Finished product specifications (90% to 110%) and in stability studies (80% to 110%).	*we would like to explain regarding your query for Benzyl Alcohol Assay finish product specifications.* *Accordingly, we explain that, for our product, the standard function of Benzyl Alcohol is antimicrobial agent. According to the <341> Antimicrobial Agents – Content USP monograph, Benzyl Alcohol limits (both release and shelf-life) can be 80.0% - 120.0%.* *"At the time of its manufacture, the product should be containing the declared amount of antimicrobial preservative (within ± 20% to allow for manufacturing and analytical variations)."* *Benzyl Alcohol release and shelf-life limits are determined based on this monograph. Both release and shelf-life limits are tighter than the limits in the USP monograph.* *For you review, the USP monograph is in attachment.*
Real time & Accelerated Stability study data of three commercial batches.	*Firm has submitted stability studies data of 2 batches (Pilot scale) both real time and accelerated for 36 months at Zone II (25±2oC/60%±5RH, 40±2oC/75%±5RH) and zone IVb conditions.* *Firm has submitted stability study data of one batch (commercial scale) both real time and accelerated for 24 months at zone II (25±2oC/60%±5RH, 40±2oC/75%±5RH) conditions.*

Decision: Keeping in view legalized GMP and Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

The firm shall submit the real time stability data on three commercial scale batches upto the demanded shelf life before issuance of Registration letter & shelf life will be granted as per the submitted real time stability study data. The Chairman Registration Board is authorized for issuance of letter after submission of said data.

2.	**Name, address of Applicant / Importer**	**M/s Calory Pharma,**

		75-B, Circular Street No. 13, Central Lane, Phase-II, DHA, Karachi.
	Details of Drug Sale License of importer	License No: 110 Address: 75-B, Circular Street No. 13, Central Lane, Phase-II, DHA, Karachi. Validity: 06-07-2023 Status: License to sell drugs by way of whole sale.
	Name and address of marketing authorization holder (abroad)	M/s 8161429 Venipharm, 422, Bureaux de la Colline F-92213 Saint-Cloud, France.
	Name, address of manufacturer(s)	M/s Centre Specialites Pharmaceutiques ZAC des Suzots 35 rue de la Chapelle F-63450 Saint-Ament Tallende, France.
	Name of exporting country	France
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• Firm has submitted legalized CoPP (No. VEN/270521/10) dated 23-06-2021 issued by Authority for Justice and Consumer Protection of the Free and Hanseatic City of Hamburg. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of the product in country of origin.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific Letter of Authorization from Qualified Person of M/s Venipharm. According to the letter, the firm M/s Venopharm authorizes "Calory Pharma Private Limited" to register, renew and to get the registration certificate for the product. The letter was issued on 17-12-2021 and valid for five years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3894 (R&I) Dated 10-02-2022
	Details of fee submitted	Rs. 150,000/- dated 04-01-2022
	The proposed proprietary name / brand name	Enoxaparin Ledraxen 4000IU (40mg)/0.4mL
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each PFS (0.4ml) contains: Enoxaparin Sodium……4000IU (equivalent to 40mg)
	Dosage form of applied drug	Solution for Injection in PFS
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	BP Specifications

	Proposed Pack size	10's PFS
	Proposed unit price	As per SRO/DPC
	Shelf Life	24 Months
	Storage Conditions	$\leq 25^0$C
	The status in reference regulatory authorities	The product is itself approved in Germany.
	For generic drugs (me-too status)	Noxane of M/s BF Biosciences (Reg. No. 107948).
	Module-II (Quality Overall Summary)	Firm has submitted ICH QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd (NKF), China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 7 batches of Drug Substance at real time conditions for 36 months, 01 batch for 12 months, 01 batch for 09 months & 01 batch for 03 months. The real time stability data conducted at 25^0C±2^0C/60±5%RH is for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted validation of Analytical methods of Anti-factor Xa activity, Anti-factor IIa Activity, Free sulfate content, Protein content, Bacterial Endotoxin, Sterility.
	Container closure system of the drug product	• A pre-filled syringe consisting of a 1-mL long barrel of type I glass with a fixed 27-gauge ½ inch stainless steel needle and a needle shield made of bromobutyl rubber • A 1-mL plunger rod made of polypropylene (which does not come directly in contact with the finished product) • A plunger stopper consisting of bromobutyl rubber
	Stability study data of drug product	Firm has submitted stability study data of 03 batches of 2000IU & 02 batches of 10000IU at real time, intermediate (Zone IVB) & conditions. The accelerated stability study data is conducted at 40±2^0C/75%RH±5% for 6 months. The real time stability study data is conducted at 25±2^0C/60%±5RH. The intermediate stability study data is conducted at 30±2^0C/65%±5RH.

3.	**Name, address of Applicant / Importer**	**M/s Calory Pharma,** **75-B, Circular Street No. 13, Central Lane, Phase-II, DHA, Karachi.**
	Details of Drug Sale License of importer	License No: 110 Address: 75-B, Circular Street No. 13, Central Lane, Phase-II, DHA, Karachi. Validity: 06-07-2023 Status: License to sell drugs by way of whole sale.
	Name and address of marketing authorization holder (abroad)	M/s 8161429 Venipharm, 422, Bureaux de la Colline F-92213 Saint-Cloud, France.
	Name, address of manufacturer(s)	M/s Centre Specialites Pharmaceutiques ZAC des Suzots 35 rue de la Chapelle F-63450 Saint-Ament Tallende, France.
	Name of exporting country	France
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• Firm has submitted legalized CoPP (No. VEN/270521/11) dated 23-06-2021 issued by Authority for Justice and Consumer Protection of the Free and Hanseatic City of Hamburg. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of the product in country of origin.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific Letter of Authorization from Qualified Person of M/s Venipharm. According to the letter, the firm M/s Venopharm authorizes "Calory Pharma Private Limited" to register, renew and to get the registration certificate for the product. The letter was issued on 17-12-2021 and valid for five years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3895 (R&I) Dated 10-02-2022
	Details of fee submitted	Rs. 150,000/- dated 04-01-2022
	The proposed proprietary name / brand name	Enoxaparin Ledraxen 6000IU (60mg)/0.6mL
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each PFS (0.6ml) contains: Enoxaparin Sodium……6000IU (equivalent to 60mg)
	Dosage form of applied drug	Solution for Injection in PFS
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	BP Specifications

	Proposed Pack size	10's PFS
	Proposed unit price	As per SRO/DPC
	Shelf Life	24 Months
	Storage Conditions	$\leq 25^0$C
	The status in reference regulatory authorities	The product is itself approved in Germany.
	For generic drugs (me-too status)	Noxane of M/s BF Biosciences (Reg. No. 107949).
	Module-II (Quality Overall Summary)	Firm has submitted ICH QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd (NKF), China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 7 batches of Drug Substance at real time conditions for 36 months, 01 batch for 12 months, 01 batch for 09 months & 01 batch for 03 months. The real time stability data conducted at 25^0C$\pm 2^0$C/60±5%RH is for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted validation of Analytical methods of Anti-factor Xa activity, Anti-factor IIa Activity, Free sulfate content, Protein content, Bacterial Endotoxin, Sterility.
	Container closure system of the drug product	• A pre-filled syringe consisting of a 1-mL long barrel of type I glass with a fixed 27-gauge ½ inch stainless steel needle and a needle shield made of bromobutyl rubber • A 1-mL plunger rod made of polypropylene (which does not come directly in contact with the finished product) • A plunger stopper consisting of bromobutyl rubber
	Stability study data of drug product	Firm has submitted stability study data of 03 batches of 2000IU & 02 batches of 10000IU at real time, intermediate (Zone IVB) & conditions. The accelerated stability study data is conducted at 40 ± 2^0C/75%RH±5% for 6 months. The real time stability study data is conducted at 25 ± 2^0C/60%±5RH. The intermediate stability study data is conducted at 30 ± 2^0C/65%±5RH.

4.	**Name, address of Applicant / Importer**	**M/s Calory Pharma,** **75-B, Circular Street No. 13, Central Lane, Phase-II, DHA, Karachi.**
	Details of Drug Sale License of importer	License No: 110 Address: 75-B, Circular Street No. 13, Central Lane, Phase-II, DHA, Karachi. Validity: 06-07-2023 Status: License to sell drugs by way of whole sale.
	Name and address of marketing authorization holder (abroad)	M/s 8161429 Venipharm, 422, Bureaux de la Colline F-92213 Saint-Cloud, France.
	Name, address of manufacturer(s)	M/s Centre Specialites Pharmaceutiques ZAC des Suzots 35 rue de la Chapelle F-63450 Saint-Ament Tallende, France.
	Name of exporting country	France
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• Firm has submitted legalized CoPP (No. VEN/270521/12) dated 23-06-2021 issued by Authority for Justice and Consumer Protection of the Free and Hanseatic City of Hamburg. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of the product in country of origin.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific Letter of Authorization from Qualified Person of M/s Venipharm. According to the letter, the firm M/s Venopharm authorizes "Calory Pharma Private Limited" to register, renew and to get the registration certificate for the product. The letter was issued on 17-12-2021 and valid for five years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3896 (R&I) Dated 10-02-2022
	Details of fee submitted	Rs. 150,000/- dated 04-01-2022
	The proposed proprietary name / brand name	Enoxaparin Ledraxen 8000IU (80mg)/0.8mL
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each PFS (0.8ml) contains: Enoxaparin Sodium……8000IU (equivalent to 80mg)
	Dosage form of applied drug	Solution for Injection in PFS
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	BP Specifications

	Proposed Pack size	10's PFS
	Proposed unit price	As per SRO/DPC
	Shelf Life	24 Months
	Storage Conditions	$\leq 25^0$C
	The status in reference regulatory authorities	The product is itself approved in Germany.
	For generic drugs (me-too status)	Noxane of M/s BF Biosciences (Reg. No. 107950).
	Module-II (Quality Overall Summary)	Firm has submitted ICH QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd (NKF), China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 7 batches of Drug Substance at real time conditions for 36 months, 01 batch for 12 months, 01 batch for 09 months & 01 batch for 03 months. The real time stability data conducted at 25^0C$\pm 2^0$C/60±5%RH is for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted validation of Analytical methods of Anti-factor Xa activity, Anti-factor IIa Activity, Free sulfate content, Protein content, Bacterial Endotoxin, Sterility.
	Container closure system of the drug product	• A pre-filled syringe consisting of a 1-mL long barrel of type I glass with a fixed 27-gauge ½ inch stainless steel needle and a needle shield made of bromobutyl rubber • A 1-mL plunger rod made of polypropylene (which does not come directly in contact with the finished product) • A plunger stopper consisting of bromobutyl rubber
	Stability study data of drug product	Firm has submitted stability study data of 03 batches of 2000IU & 02 batches of 10000IU at real time, intermediate (Zone IVB) & conditions. The accelerated stability study data is conducted at 40 ± 2^0C/75%RH±5% for 6 months. The real time stability study data is conducted at 25 ± 2^0C/60%±5RH. The intermediate stability study data is conducted at 30 ± 2^0C/65%±5RH.

The firm has submitted the following data as per requirements of 289th meeting of Registration Board:

Sr. No.	Required Documents	Documents Provided by the Firm
1.	Equivalence of physicochemical properties, such as:	
	c. Molecular weight distribution using size exclusion chromatography	v. Molecular mass distribution and proportion vi. %1, 6-anhydro derivatives vii. Free sulphate content viii. Ratio of sulfate ions to carboxylate ions ix. UV Absorption and specific absorbance at 231 nm
	d. Chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).	vi. Chain mapping by Gel Filtration Chromatography (GFC) vii. Chain mapping by strong anion exchange HPLC (SAX-HPLC) viii. Proton nuclear magnetic resonance (1H-NMR) ix. Heteronuclear single quantum coherence (HSQC) x. Intact chain mapping by LCMS
2.	Equivalence of heparin source material (i.e. heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (i.e. cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.	• Fresh pig's small intestine is collected and squeezed to get porcine intestinal mucosa. Porcine intestinal mucosa is then digested and heparin is adsorbed on an ion exchange resin (Intermediate A). • After the washing and elution of the resin, further steps of precipitation and drying lead to crude heparin (Intermediate B). • Crude heparin (Intermediate B) is dissolved in water, submitted to enzymolysis and then purified on resins. Heparin sodium (Intermediate C) is obtained after several steps including oxidation, ultra-filtration, fractionation and a final precipitation in ethanol. • Enoxaparin sodium is manufactured in three stages, starting from the heparin sodium which undergoes a step of salification to get the quaternary ammonium salt of heparin (Intermediate I). The salification step is followed by an esterification step to form the ester salt of heparin (Intermediate II). Enoxaparin sodium is finally isolated after depolymerization and purification steps.
3.	Equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by following: g. Capillary Electrophoresis (CE) h. Reverse phase high-performance liquid chromatography (RP-HPLC) i. Strong anion exchange HPLC (SAX-HPLC) j. Mass spectroscopy k. Nuclear magnetic resonance (NMR) spectroscopy. l. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-	ix. Disaccharide building block by strong anion exchange HPLC (SAX-HPLC) x. Fragment mapping (Heparinase I/II/III) by strong anion exchange HPLC (SAX-HPLC) xi. Fragment mapping (heparinase I/II/III) by liquid chromatography – mass spectrometry (LC-MS) xii. Dp6 mapping (heparinase I/II/III) by liquid chromatography – mass spectrometry (LC-MS) xiii. Dp8 mapping (heparinase I/II/III) by liquid chromatography – mass spectrometry (LC-MS) xiv. Dp10 mapping (heparinase I/II/III) by liquid chromatography – mass spectrometry (LC-MS) xv. Nitrous acid (HONO) depolymerisation disaccharide mapping by liquid chromatography – mass spectrometry (LC-MS) xvi. Tetrasaccharides (dp4) analysis by strong anion exchange HPLC (SAX-HPLC) vii. Tetrasaccharides (dp4) sequences by reversed-phase ion-pair liquid chromatography- electrospray ionization - mass spectrometry (RPIP-ESI-MS and RPIP-ESI-MS/MS) viii. Oligosaccharide mapping by liquid chromatography – mass spectrometry (LC-MS) (dp6/8/10)

	sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.	
4.	Equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	iii. Anti-factor Xa & Anti-factor IIa activity by using Biophen Heparin Anti-Xa (2 Stages) and Biophen Heparin Anti-IIa (2 Stages) commercial kits. iv. The anticoagulant activity of the biosimilar enoxaparin drug product is analyzed and compared with Lovenox®/Clexane® based on aPTT (Activated Partial Thromboplastin Time) and Heptest prolongation time v.
5.	Equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.	A monocentric, randomized, open-label, single-dose, two-period, crossover study to assess the pharmacokinetic and pharmacodynamic equivalence of Reference Product Lovenox® 10000 IU/1 mL solution for injection in prefilled syringe and test formulation of Enoxaparin Ledraxen 10.000 IE (100 mg)/1 ml Injektionslösung in einer Fertigspritze following subcutaneous administration in healthy subjects in fasting conditions

Remarks of Evaluator	• The address of product license holder is different on CoPP from SmPC available on official website of Germany & letter of authorization. • The batch release site is different in dossier from Public Assessment Report available on official website of Germany & from Form-5F. • The manufacturer as per submitted CoPP is **M/s Centre Specialites Pharmaceutiques ZAC des Suzots 35 rue de la Chapelle F-63450 Saint-Ament Tallende, France** while as per submitted dossier manufacturer is **M/s Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd (NKF), No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China**. • Firm has not submitted the verification of compendial analytical methods of drug product. • Firm has not submitted the real time and accelerated stability data of applied strengths. However, stability data of lower (2000IU) & higher strengths (10000IU) is provided. • Stability study data of only 02 batches of higher strength i.e. 10000IU is provided. • Related substances are not tested in real time, intermediate & accelerated stability data while 1,6-anhydro derivatives, Average Mass & Sodium content are only tested for 01 batch of each strength. • **The provided intermediate/ Zone IVB stability data is for 36 months for two batches of lower strength & one batch of higher strength and 12 months of one batch each of lower & higher strength**. • **All the batches of both strengths get out of specifications after 12 months at intermediate/ Zone IVB conditions.**

Decision: Registration Board deferred the products at S.No. 2,3 & 4 for submission of following by the firm:

i. Difference in address of product license holder on CoPP from SmPC available on official website of Germany & letter of authorization.
ii. Difference in batch release site in dossier from Public Assessment Report available on official website of Germany & from Form-5F.
iii. Any legalized evidence issued by regulatory authority of country of origin indicating that the manufacturer of product registered in Germany is M/s Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd (NKF), No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China while M/s Centre Specialites Pharmaceutiques ZAC des Suzots 35 rue de la Chapelle F-63450 Saint-Ament Tallende, France is only batch release site.
iv. Verification reports of compendial analytical methods of drug product.
v. Real time & Accelerated stability data of three commercial batches of 2000IU & 10000IU upto the shelf life including all parameters as per finished product specification.
vi. Clarification is required as all the batches of both strengths get out of specification after 12 months of storage at 30 ± 2^0C/65%±5RH.

Evaluation by DBE&R:

Reply of firm against each query is summarized in table below for consideration of the Board.

Queries	Response by the firm

	Difference in address of product license holder on CoPP from SmPC available on official website of Germany & letter of authorization.	The address for Venipharm (product License Holder) mentioned in CoPP is ***422 Bureaux de la Colline F-92213 Saint-Cloud France*** and address mentioned in LoA & SmPC is ***4 Bureaux de la Colline 92210 Saint-Cloud France.*** We confirmed that these both addresses are well correct for Venipharm's (Product License Holder) office. The address on CoPP (***422 Bureaux de la Colline F-92213 Saint-Cloud France*** is more detailed version)
	Difference in batch release site in dossier from Public Assessment Report available on official website of Germany & from Form-5F.	In PAR available on MHRA website, no information regarding batch release site is available. Also we would like to inform one change that was approved by BfARM, Germany. At time of our registration in EU first, the batch release site was **Melbourn Scientific Limited (United Kingdom)**. *Due to Brexit, we had to change the batch release site from **Melbourn Scientific Limited (United Kingdom)** to **Centre Specialites Pharmaceutiques (France)** via a dedicated variation submission.* May be the website you are checking may still not be updated and you may still see Melbourn Scientific Limited (United Kingdom). We confirm that there is only one batch release site for our products which is Centre Specialites Pharmaceutiques (France). For your reference we have attached cop of variation approval letter received from Bfarm.
	Any legalized evidence issued by regulatory authority of country of origin indicating that the manufacturer of product registered in Germany is M/s Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd (NKF), No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China while M/s Centre Specialites Pharmaceutiques ZAC des Suzots 35 rue de la Chapelle F-63450 Saint-Ament Tallende, France is only batch release site.	Firm has submitted a copy of CoPP issued to Israel showing manufacturer responsible for manufacturing and packaging M/s Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd (NKF), No. 16 Xuefu Road, Nanjing High & New Technology Development Zone, Nanjing, China
	Verification reports of compendial analytical methods of drug product.	We confirm that validation study for Compendial Analytical methods (Appearance, Clarity, Coloration, UV absorption, Identification, assay of sodium, molecular mass distribution and mass-average relative molecular mass, determination of the pH, related substances, extractable volume, particulate matter and Specific absorbance) were NOT performed as the principal of these analytical methods are Exactly same as described in the Ph. Eur. General monographs. Moreover, if any adjustment done according to Ph.Eur. 2.2.46, No Analytical validation study is required.
	Real time & Accelerated stability data of three commercial batches of 2000IU & 10000IU up to the shelf life including all parameters as per finished product specification.	Firm has referred to bracketing design of ICH guidelines and submitted stability studies of three batches of 2000IU two batches of 10000 IU both real time and accelerated at 25 ± 2^0C/60%±5RH & 40 ± 2^0C/75%±5RH.
	Clarification is required as all the batches of both strengths get out of specification after 12 months of storage at 30 ± 2^0C/65%±5RH.	After storage of the finished product at 30^0C/65% RH, **the major change is for the Color which is out of specification after 12 months**. *If we consider the results of the forced degradation study in heat conditions (after one day or after 10 days at 80^0C). Change of color of solution was considered as Stability Indicator. So result of ICH stability at intermediate temperature (30^0C) are confirming the*

	results obtained during the forced degradation study in heat conditions. *The conclusion is that Enoxaparin sodium, solution for injection is NOT stable at 30^0C/65% RH. All the available results got at 25^0C/60% RH after 36 months are compliant with the specifications. Hence, a shelf life of 36 months is claimed with a temperature restriction for the finished product packaged in prefilled syringes Do not store above 25^0C.* *A commitment is also attached defining the temperature restriction.*

For stability studies firm has referred to bracketing design as per ICH guidelines which is as follow:

2.3 Bracketing

Bracketing is the design of a stability schedule such that only samples on the extremes of certain design factors (e.g., strength, container size and/or fill) are tested at all-time points as in a full design. The design assumes that the stability of any intermediate levels is represented by the stability of the extremes tested. The use of a bracketing design would not be considered appropriate if it cannot be demonstrated that the strengths or container sizes and/or fills selected for testing are indeed the extremes.

2.3.1 Design Factors

Design factors are variables (e.g., strength, container size and/or fill) to be evaluated in a study design for their effect on product stability.

2.3.1.1 Strength

Bracketing can be applied to studies with multiple strengths of identical or closely related formulations. Examples include but are not limited to (1) capsules of different strengths made with different fill plug sizes from the same powder blend, (2) tablets of different strengths manufactured by compressing varying amounts of the same granulation, and (3) oral solutions of different strengths with formulations that differ only in minor excipients (e.g., colorants, flavorings). With justification, bracketing can be applied to studies with multiple strengths where the relative amounts of drug substance and excipients change in a formulation. Such justification can include a demonstration of comparable stability profiles among the different strengths of clinical or development batches. In cases where different excipients are used among strengths, bracketing generally should not be applied.

2.3.1.2 Container Closure Sizes and/or Fills

Bracketing can be applied to studies of the same container closure system where either container size or fill varies while the other remains constant. However, if a bracketing design is considered where both container size and fill vary, it should not be assumed that the largest and smallest containers represent the extremes of all packaging configurations. Care should be taken to select the extremes by comparing the various characteristics of the container closure system that may affect product stability. These characteristics include container wall thickness, closure geometry, surface area to volume ratio, headspace to volume ratio, water vapor permeation rate or oxygen permeation rate per dosage unit or unit fill volume, as appropriate. With justification, bracketing can be applied to studies for the same container when the closure varies. Justification could include a discussion of the relative permeation rates of the bracketed container closure systems.

2.3.2 Design Considerations and Potential Risks

If, after starting the studies, one of the extremes is no longer expected to be marketed, the study design can be maintained to support the bracketed intermediates. A commitment should be provided to carry out stability studies on the marketed extremes post-approval. Before a bracketing design is applied, its effect on the retest period or shelf life estimation should be assessed. If the stability of the extremes is shown to be different, the intermediates should be considered no more stable than the least stable extreme (i.e., the shelf life for the intermediates should not exceed that for the least stable extreme).

Example of bracketing design as per ICH is as under:

This example is based on a product available in three strengths and three container sizes. In this example, it should be demonstrated that the 15 ml and 500 ml high-density polyethylene container sizes truly represent the extremes. The batches for each selected combination should be tested at each time point as in a full design.

Strength	**50mg**			**75mg**			**100mg**		
Batch	1	2	3	1	2	3	1	2	3

Container size	**15ml**	T	T	T				T	T	T
	100ml									
	500ml	T	T	T				T	T	T

In case of firm submitted stability studies is as follow:

Strength		**20mg/0.2ml (2000IU/ml)**			**40mg/0.4ml (4000IU/ml)**			**60mg/0.6ml (6000IU/ml)**			**80mg/0.8ml (8000IU/ml)**			**10mg/1ml (10,000IU/m**		
Batch		1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
Container size	**1ml(0.2ml)**	T	T	T										T	T	--
	1ml(0.4ml)															
	1ml(0.6ml)															
	1ml(0.8ml)															
	1ml (1ml)	T	T	T										T	T	--

Firm has further submitted data of following commercial batches as per following details:

Strength	**Data**	**Conditions**
4000IU	36 months Real time/6 month Accelerated	25 ± 2^0C/60%±5RH. 40 ± 2^0C/75%±5RH.
2000IU	18 months Real time/6 month Accelerated	25 ± 2^0C/60%±5RH. 40 ± 2^0C/75%±5RH.
10000IU	18 months Real time/6 month Accelerated	25 ± 2^0C/60%±5RH.

Decision: Registration Board deferred the case for following points:

a. Submission of real time stability data of three commercial batches up to the demanded shelf life as per ICH guidelines.

b. Submission of valid legalized CoPP indicating actual product License Holder, manufacturer and batch release site.