MINUTES OF 327th MEETING OF REGISTRATION BOARD HELD ON 13TH APRIL, 2023

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Drug Regulatory Authority of Pakistan
T.F. Complex, Mauve Area, G-9/4
Islamabad.

327th meeting of Registration Board was held on 13th April, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad.

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

Following members attended the meeting:

1.	Ch. Zeeshan Nazir Bajar, Additional Director (PE&R), DRAP.	Member/ Secretary
2.	Lt. Gen.(R) Prof. Dr. Karamat A. Karamat (HI-M.SI-M), Former Surgeon General Pakistan.	Co-opted Member (Online)
3.	Maj. Gen. (R) Dr. Tahir Mukhtar Sayed, Inspector General (Hospitals), Fauji Foundation, Rawalpindi	Co-opted Member (Online)
4.	Mr. Ajmal Sohail, Director (QA&LT), DRAP, Islamabad	Member
5.	Mr. Muhammad Aslam, Additional Draftsman, Ministry of law & Justice, Islamabad.	Member (Online)
6.	Mr. Ghulam Mujtaba, Rep. of IPO, Islamabad	Member (Online)
7.	Dr. Imranullah Khan, Senior Drug Analyst, DTL, Govt. of KP, Peshawar	Member
8.	Dr. Ali Jan, Director, DTL, Govt. of Baluchistan	Member
9.	Dr. Asad Íbrar, Director DTL Govt. of Punjab, Bahawalpur	Member
10.	Syed Adnan Rizvi, Rep. of Director DTL. Govt. of Sindh. Karachi	Member (Online)
11.	Mr. Muhammad Kashif, Deputy Director, Representative of Biological Evaluation & Research Division, DRAP	Member
12.	Mrs. Sadaf Ahmad, Assistant Director, Rep of MD&MC Division.	Member
13.	Dr. Qurban Ali, Veterinary Expert,	Coopted Member (Online)

Mr. Nadeem Alamgir (Pharma Bureau), Mr. Hamid Raza (Online) & Mr. Jalal Zafar (PPMA), Mr. Ziaulhaq & Mr. Amir (PCDA) attended the meeting as observers.

Item No. I Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
1.	Mr. Ammar Ashraf Awan	Evaluator PEC-II
2.	Dr. Muhammad Haseeb Tariq	Evaluator PEC-III
3.	Mst. Farzana Raja	Evaluator PEC-IV
4.	Mst. Iqra Aftab	Evaluator PEC-V
5.	Mr. Adil Saeed	Evaluator PEC-IX
6.	Ms. Najia Saleem	Evaluator PEC-X
7.	Dr. Farhadullah	Evaluator PEC-XI
8.	Mr. Shahid Nawaz	Evaluator PEC-XIII
9.	Ms. Saima Hussain	Evaluator PEC-XV
10.	Ms. Sana Kanwal	Evaluator PEC-XX
11.	Mr. Tahir Waqas	Evaluator PEC-XXI
12.	Mr. Hafiz Sanaullah Babar	Evaluator PEC-XXII
13.	Ms. Maham Misbah	Evaluator PEC-XXIII
14.	Mr. Muneeb Ahmed Cheema	Deputy Director (PE&R)
15.	Mr. Ishtiaq	Ex AD PEC

Evaluator PEC-II

Case no. 01 Registration applications of newly granted DML or New section (Human)

a. New DML

1.	**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	☒ Do mestic 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 5899 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 02-03-2023
	The proposed proprietary name / brand name	**Ezole 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	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	Approved by US FDA
	For generic drugs (me-too status)	Nexum 20 mg cap of M/s Getz pharma (Reg.# 033891)
	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 Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta 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, 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	Both accelerated & long-term stability studies from M/s Vision Pharma has been submitted for Esomeprazole EC pellets as per Zone IVa conditions.
	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 & CDP studies against the comparator product of "Nexum Capsules" in 0.1N HCl & PH 6.8 buffer dissolution mediums have been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Method validation studies have been submitted.

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.	EMZ046493		
Description of Pack (Container closure system)	Alu-Alu foil 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.	Trial 01	Trial 02	Trial 03
Batch Size	1500 capsules	1500 capsules	1500 capsules
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)	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
2.	**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 5900 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 02-03-2023
	The proposed proprietary name / brand name	**Ezole 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	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	Approved by US FDA
	For generic drugs (me-too status)	Nexum 40 mg cap of M/s Getz 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.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta 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, 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	Both accelerated & long-term stability studies from M/s Vision Pharma has been submitted for Esomeprazole EC pellets as per Zone IVa conditions.
	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 & CDP studies against the comparator product of "Nexum Capsules" in 0.1N HCl & PH 6.8 buffer dissolution mediums have been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Method validation studies have been submitted.

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.	EMZ046493
Description of Pack (Container closure system)	Alu-Alu foil 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.	Trial 01	Trial 02	Trial 03
Batch Size	1500 capsules	1500 capsules	1500 capsules
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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
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.	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.	Firm has submitted drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies 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.	Submitted.
3.2.P.5	Clarification shall be submitted that which test of Dissolution has been applied from the USP monograph of "Esomeprazole Magnesium Delayed-Release Capsules"	Firm has referred to USP Dissolution Test 1 from the USP monograph of "Esomeprazole Magnesium Delayed-Release Capsules"
3.2.P.5.3	• Performance of specificity parameter shall be submitted in analytical method verification studies. • Concentrations in terms of mg/ml shall be submitted for the performance of accuracy parameter.	• Performance of specificity parameter gas been submitted. • Concentrations in terms of mg/ml for the performance of accuracy parameter has been submitted.
3.2.P.8	• Complete batch manufacturing record of three stability batches shall be submitted. • Raw data sheets for the performance of dissolution test during stability studies shall be submitted.	Submitted.

Decision: Registration Board approved the applications of Ezole 40mg Capsule & Ezole 20mg Capsule. • **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 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 5901 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 02-03-2023
	The proposed proprietary name / brand name	**Ezole 40mg Dry powder Vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Esomeprazole Sodium Eq. to Esomeprazole…..40mg
	Pharmaceutical form of applied drug	Dry powder 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	Approved by MHRA of UK
	For generic drugs (me-too status)	Acireg of Barret hodgson Pakistan
	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 Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta 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, 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	Both accelerated & long-term stability studies from M/s Vision Pharma has been submitted for Esomeprazole EC pellets as per Zone IVa conditions.
	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 against the comparator product of "Nexum Injection" has been submitted.
	Analytical method validation/verification of product	Method validation studies have been submitted.

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.	2112901		
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.	Trial 01	Trial 02	Trial 03
Batch Size	1000 vials	1000 vials	1000 vials
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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
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.	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.4.4	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.2.6	Compatibility studies with the diluent shall be submitted.	Submitted.
3.2.P.5	• Justification shall be submitted for the specifications of "filled weight per vial." • Analytical procedure for the drug product testing shall be submitted.	• Firm has justified the filled weight per unit vial against the potency of drug substance determined during drug substance analysis. • Submitted.
3.2.P.8	• Complete batch manufacturing record of three stability batches shall be submitted.	• 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.**

Case no. 02 Registration applications of Form 5F (Human)

4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceutical, 7Km Pasrur Road Sialkot, Islamabad 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
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy. No 6961 dated 02-03-2021
	Details of fee submitted	Rs.50,000/- dated 18-01-2021
	The proposed proprietary name / brand name	**Celine Injection 500mg IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone … 500mg
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, 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, 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, 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} ± 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. (Batch No. 011302001, 011302002, 011302003)
	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 against the product Rocephin 500mg injection.
	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 Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China		
API Lot No.	2081704066		
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.	VP-1436	VP-1462	VP-1319
Batch Size	40,000 Vials	40,000 Vials	40,000 Vials
Manufacturing Date	01-2018	02-2018	04-2018
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# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.
4	Data of stability batches will be 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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks:

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 500mg IV instead of 500mgIM.

Firm has submitted revised stability data for new batches detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-299	10-2019	10-2021	30-10-2019	33,333 vials
VP-300	10-2019	10-2021	30-10-2019	33,333 vials
VP-301	10-2019	10-2021	30-10-2019	33,333 vials

Decision: Approved. Firm shall submit full fee of Rs. 75,000/- for revision of stability studies data as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021 before issuance of registration letter.

- **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.**

5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceutical, 7Km Pasrur Road Sialkot, Islamabad 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
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy. No 7164 dated 04-03-2021
	Details of fee submitted	Rs.50,000/- dated 18-01-2021
	The proposed proprietary name / brand name	**Celine Injection 1g IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone … 1gm
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, 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, 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, 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} ± 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. (Batch No. 011302001, 011302002, 011302003)
	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 against the product Rocephin 1gm IM injection.

	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 Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China		
API Lot No.	2081704052		
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.	VP-1613	VP-1560	VP-1457
Batch Size	40,000 Vials	40,000 Vials	40,000 Vials
Manufacturing Date	07-2018	05-2018	02-2018
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# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.
4	Data of stability batches will be 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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks:

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 1gm IV and 1gm IM application.

Firm has submitted revised stability data for new batches detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-173	07-2019	07-2021	28-07-2019	33,333 vials
VP-174	07-2019	07-2021	28-07-2019	33,333 vials
VP-175	07-2019	07-2021	28-07-2019	33,333 vials

Decision: Approved. Firm shall submit full fee of Rs. 75,000/- for revision of stability studies data as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021 before issuance of registration letter. • **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 Bio-Next Pharmaceuticals.** **Plot No. 50, Street No. S-10, RCCI, Rawat**
	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
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 6959 dated 02-03-2021
	Details of fee submitted	Rs.50,000/- dated 23-04-2020
	The proposed proprietary name / brand name	**Nextone Injection 1g IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone … 1gm
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, 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, 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, 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} ± 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. (Batch No. 011302001, 011302002, 011302003)
	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 against the product Rocephin 1gm IM injection.
	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 Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China		
API Lot No.	2081704052		
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.	VP-1613	VP-1560	VP-1457

Batch Size	40,000 Vials	40,000 Vials	40,000 Vials
Manufacturing Date	07-2018	05-2018	02-2018
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# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.
4	Data of stability batches will be 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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks: The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad have already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:

Applicant firm	M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2- Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad
Brand Name	CEFEXO 1g Injection IV
Batch No. of drug product	VP-1457,VP-1560,VP-1613
Case No.	750
RB meeting	316

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 Bio-Next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat**
	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
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 7098 dated 03-03-2021
	Details of fee submitted	Rs.50,000/- dated 23-04-2020
	The proposed proprietary name / brand name	**Nextone Injection 250mg IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium Eq. to Ceftriaxone … 250mg
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals 025876
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, 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, 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, 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} ± 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. (Batch No. 011302001, 011302002, 011302003)
	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 against the product Tuff 250mg Injection of M/s Healthtek (Pvt.) Ltd.
	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 Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China		
API Lot No.	2081704061		
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.	VP-1522	VP-1523	VP-1660
Batch Size	40,000 Vials	40,000 Vials	40,000 Vials
Manufacturing Date	04-2018	05-2018	08-2018
Date of Initiation	05-05-2018	04-06-2018	19-09-2018
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# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.

4	Data of stability batches will be 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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks: The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad have already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:

Applicant firm	M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2- Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad
Brand Name	CEFEXO 250mg Injection IM
Batch No. of drug product	VP-1522,VP-1523,VP-1660
Case No.	748
RB meeting	316

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.**

8.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat**
	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
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 6958 dated 02-03-2021
	Details of fee submitted	Rs.50,000/- dated 23-04-2020
	The proposed proprietary name / brand name	**Nextone Injection 500mg IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone … 500mg
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Antibiotic

	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, 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, 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, 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} ± 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. (Batch No. 011302001, 011302002, 011302003)
	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	Firm has performed pharmaceutical equivalence

	dissolution profile	against the product Rocephin 500mg injection.
	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 Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China		
API Lot No.	2081704066		
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.	VP-1436	VP-1462	VP-1319
Batch Size	40,000 Vials	40,000 Vials	40,000 Vials
Manufacturing Date	01-2018	02-2018	04-2018
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# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.
4	Data of stability batches will be 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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks:

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 500mg IV instead of 500mgIM.

Firm has submitted revised stability data for new batches detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-299	10-2019	10-2021	30-10-2019	33,333 vials
VP-300	10-2019	10-2021	30-10-2019	33,333 vials
VP-301	10-2019	10-2021	30-10-2019	33,333 vials

Decision: Approved. Firm shall submit full fee of Rs. 75,000/- for revision of stability studies data as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021 before issuance of registration letter.

- **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 Davis Pharmaceuticals Laboratories. Plot No. 121, 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
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 7096 dated 03-03-2021
	Details of fee submitted	Rs.50,000/- dated 28-12-2020
	The proposed proprietary name / brand name	**Ceftione 500mg IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone … 500mg
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.

	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, 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, 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, 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} ± 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. (Batch No. 011302001, 011302002, 011302003)
	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 against the product Rocephin 500mg injection.
	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 Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China
API Lot No.	2081704066

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.	VP-1436	VP-1462	VP-1319
Batch Size	40,000 Vials	40,000 Vials	40,000 Vials
Manufacturing Date	01-2018	02-2018	04-2018
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# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.
4	Data of stability batches will be 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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks:

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 500mg IV instead of 500mgIM.

Firm has submitted revised stability data for new batches detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-299	10-2019	10-2021	30-10-2019	33,333 vials
VP-300	10-2019	10-2021	30-10-2019	33,333 vials
VP-301	10-2019	10-2021	30-10-2019	33,333 vials

Decision: Approved. Firm shall submit full fee of Rs. 75,000/- for revision of stability studies data as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021 before issuance of registration letter.

- **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**	**M/s Davis Pharmaceuticals Laboratories.**

	Authorization Holder	**Plot No. 121, 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
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 7103 dated 03-03-2021
	Details of fee submitted	Rs.50,000/- dated 28-12-2020
	The proposed proprietary name / brand name	**Ceftione Injection 1g IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone … 1gm
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, 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, 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, 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} ± 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. (Batch No. 011302001, 011302002, 011302003)
	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 against the product Rocephin 1gm IM injection.
	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 Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China		
API Lot No.	2081704052		
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.	VP-1613	VP-1560	VP-1457
Batch Size	40,000 Vials	40,000 Vials	40,000 Vials
Manufacturing Date	07-2018	05-2018	02-2018
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# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.
4	Data of stability batches will be 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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks:

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 1gm IV instead of 1gm IM application.

Firm has submitted revised stability data detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-173	07-2019	07-2021	28-07-2019	33,333 vials
VP-174	07-2019	07-2021	28-07-2019	33,333 vials
VP-175	07-2019	07-2021	28-07-2019	33,333 vials

Decision: Approved. Firm shall submit full fee of Rs. 75,000/- for revision of stability studies data as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021 before issuance of registration letter.

- **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, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, 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
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 7102 dated 03-03-2021

	Details of fee submitted	Rs.50,000/- dated 28-12-2020
	The proposed proprietary name / brand name	**Ceftione Injection 250mg IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium Eq. to Ceftriaxone … 250mg
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals 025876
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, 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, 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, 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} ± 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. (Batch No. 011302001, 011302002, 011302003)

	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 against the product Tuff 250mg IV Injection of M/s Healthtek (Pvt.) Ltd.
	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 Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China		
API Lot No.	2081704061		
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.	VP-1522	VP-1523	VP-1660
Batch Size	40,000 Vials	40,000 Vials	40,000 Vials
Manufacturing Date	04-2018	05-2018	08-2018
Date of Initiation	05-05-2018	04-06-2018	19-09-2018
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# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.
4	Data of stability batches will be 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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2.S.4	• Justification shall be submitted regarding drug substance specifications & analytical procedure proposed by the drug substance manufacturer, whether it is as per USP or Chinese pharmacopoeia. • Assay limits proposed in the drug substance specifications proposed by the drug substance manufacturer are not as per USP monograph for "Ceftriaxone sodium". • Copy of drug substance specifications and analytical procedure applied by Drug product manufacturer shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	• Firm has declared drug substance specifications as per USP. • Firm has submitted revised specifications from drug substance manufacturer i.e., M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd., with Assay limits as per USP. • Analytical method verification studies report has been 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 / /Active Pharmaceutical Ingredient manufacture.	• Firm has submitted that the Assay results are for the Ceftriaxone base only. • Firm has submitted that the Assay results are for the Ceftriaxone base only. • COA of drug substance submitted from M/s Bio Lab & M/s Sinopharm
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided	Firm has submitted COA of working standard from M/s Bio-labs
3.2.P.2.2.1	Test of water determination has not been performed in "Pharmaceutical equivalence" studies.	Firm has submitted revised Pharmaceutical equivalence studies wherein test of water determination has been added.
3.2.P.2.6	Compatibility study with the reconstitution diluent shall be submitted.	Submitted.
3.2.P.5.1	• Submit the document of Drug product specifications and Drug product testing method in use by M/s Bio-Labs.	• Firm has submitted analytical procedure as per USP monograph.
3.2.P.6	Submit readable copy of COA of primary / secondary reference standard applied for the analysis during stability studies.	Firm has submitted COA of working standard from M/s Bio-labs
3.2.P.8	• Documents for the procurement of API with approval from DRAP for the relevant batch# of drug substance which has beenused to formulate stability batches. • 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. • Complete Batch Manufacturing Records of drug product stability batches shall be submitted.	• Firm has submitted copy of commercial invoice specifying import of 1200Kg Ceftriaxone sodium (sterile) from Sinopharm dated 22-12 2017. The invoice specifies multiple batches of Ceftriaxone. In which the quantity of lot No. Q011711032 is 250kg. Firm has submitted raw data sheets and stability summary sheets, wherein previously test of sterility, particulate matter and water

		content has been included in previously submitted sheets. • BMRs have been submitted.

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

- **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, address of Applicant / Marketing Authorization Holder	**M/s Daneen Pharma Private Limited** **27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	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 672 dated 07-01-2022
	Details of fee submitted	Rs.75,000/- dated 25-11-2021
	The proposed proprietary name / brand name	**Dapazin 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	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Farxiga tablet of USFDA approved

<table>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Dapaglu 10mg tablet of M/s Scotmann</td></tr>
<tr><td></td><td>GMP status of the Finished product manufacturer</td><td>New GMP granted on 07/10/2021
Tablet section (General & Psycotropic) approved.</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Jiangsu Yogan Pharmaceutical Co., Ltd, China</td></tr>
<tr><td></td><td>Module-II (Quality Overall Summary)</td><td>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.</td></tr>
<tr><td></td><td>Module III (Drug Substance)</td><td>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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance</td></tr>
<tr><td></td><td>Stability studies</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.</td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>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.</td></tr>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td>Firm has submitted Comparative dissolution study of their product (Flucid Tablets) with Innovator’s Brand “Forxiga Tablets” The details are as follows:
<table>
<tr><td>Feature</td><td>Reference. Product</td><td>Product Genix</td></tr>
<tr><td>Brand Name</td><td>Forxiga 10mg Tablet</td><td>Flucid 10mg</td></tr>
<tr><td>Batch No.</td><td>AAP0252</td><td>19SB-204-01</td></tr>
<tr><td>Mfg. Date</td><td>10/2016</td><td>01-2019</td></tr>
<tr><td>Exp. Date</td><td>09/2019</td><td>01-2021</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></td><td>Analytical method validation/verification of product</td><td>Method validation studies have submitted including linearity, range, accuracy, precision, specificity.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
</table>

Manufacturer of API	M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China		
API Lot No.	DPG-201803001		
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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 1,2 ,3,4 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.	19SB-204-01	19SB-205-02	19SB-206-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	24-01-2019	24-01-2019	24-01-2019
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.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.
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^{II}:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 296th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 296th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 296th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Fludip 10mg tablet

Batch No. of drug product	19SB-204-01 19SB-205-02 19SB-206-03
Case No.	3
Registration Board meeting	296th meeting of Registration Board held on 8-9th September, 2020.

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 296th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Forxiga tablet.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Pharmaceutical Equivalence studies.
- Process validation protocol.
- Analytical method validation studies for drug product.

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.**

13.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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 1014 dated 11-01-2022
	Details of fee submitted	Rs.75,000/- dated 25-11-2021
	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 Eq. to Dapagliflozin……5mg
	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO

<table>
<tr><td></td><td>Proposed unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Farxiga tablet of USFDA approved</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Dapaglu 5mg tablet of M/s Scotmann</td></tr>
<tr><td></td><td>GMP status of the Finished product manufacturer</td><td>New GMP granted on 07/10/2021
Tablet section (General & Psycotropic) approved.</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Jiangsu Yogan Pharmaceutical Co., Ltd, China</td></tr>
<tr><td></td><td>Module-II (Quality Overall Summary)</td><td>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.</td></tr>
<tr><td></td><td>Module III (Drug Substance)</td><td>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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance</td></tr>
<tr><td></td><td>Stability studies</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.</td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>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.</td></tr>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td>Firm has submitted Comparative dissolution study of their product (Flucid Tablets) with Innovator’s Brand “Forxiga Tablets” The details are as follows:
Feature Reference. Product Product Genix
<table>
<tr><td>Feature</td><td>Reference. Product</td><td>Product Genix</td></tr>
<tr><td>Brand Name</td><td>Forxiga 5mg Tablet</td><td>Flucid 5mg</td></tr>
<tr><td>Batch No.</td><td>NJ535</td><td>19SB-201-01</td></tr>
<tr><td>Mfg. Date</td><td>03/2017</td><td>01-2019</td></tr>
<tr><td>Exp. Date</td><td>02/2020</td><td>01-2021</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
pH 1.2 HCl buffer
pH 4.5 Acetate buffer</td></tr>
</table>

		pH 6.8 Phosphate buffer		
	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 Jiangsu Yogan Pharmaceutical Co., Ltd, China		
API Lot No.		DPG-201803001		
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: 24 months Accelerated: 6 months		
Frequency		Accelerated: 1,2 ,3,4 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.		19SB-201-01	19SB-202-02	19SB-203-03
Batch Size		1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date		01-2019	01-2019	01-2019
Date of Initiation		21-01-2019	21-01-2019	21-01-2019
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.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.		
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[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 296th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 296th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 296th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Fludip 5mg tablet
Batch No. of drug product	19SB-201-01 19SB-202-02 19SB-203-03
Case No.	2
Registration Board meeting	296th meeting of Registration Board held on 8-9th September, 2020.

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 296th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Forxiga tablet.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Pharmaceutical Equivalence studies.
- Process validation protocol.
- Analytical method validation studies for drug product.

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.**

14.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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 30263 dated 05-11-2021
	Details of fee submitted	PKR 75,000/-: dated 12/10/2021
	The proposed proprietary name / brand name	**Erglif-M Tablets 2.5mg/1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin……....2.5mg Metformin HCl……..1000mg

	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Reference to Finished product specifications	Innovator Specification
	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	SEGLUROMET tablet 2.5mg/1000mg by Merck & Co. Inc, USA (USFDA Approved)
	For generic drugs (me-too status)	LOZGIL -M Tablets 2.5mg/1000mg by Genix Pharma Private Limited.
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Tablet section (General & Psycotropic) approved.
	Name and address of API manufacturer.	**Ertugliflozin:** Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd **Address:** Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China **Metformin HCL:** Abhilash Chemicals and Pharmaceuticals Private Limited, **Address:** 34/6A, Nayakkanpatti Village, Madurai North Taluk, Madurai. Pin Code – 625301. Tamil Nadu, 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)	Drug substances is tested at **Ertugliflozin** on in-house specifications & **Metformin HCL** on USP Specifications. 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Ertugliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ETG20161201, ETG20161202 & ETG20170101) **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: (MET/06/00546, MET/06/00547 &

		MET/06/00548)
	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 **SEGLUROMET tablet 2.5mg/1000mg** (Batch no: S037765) by Merck & Co. Inc by performing quality tests (Identification, Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is **SEGLUROMET tablet 2.5mg/1000mg** Merck & Co. Inc in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was in 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	**Ertugliflozin:** Shanghai Pharma Group Changzhou kony Pharmaceuticals Co., Ltd China Daixi street, Luoyang town, Wujin District, Changzhou, Jiangsu, China **Metformin hydrochloride:** Abhilash Chemicals and Pharmaceuticals Pvt. Ltd. 34/6A, Nayakanpatti village, Madurai North Taluk Madurai Tamilnadu India.		
API Lot No.	**Ertugliflozin**: ETG20180901, **Metformin HCL**: MET/B/01/19030070		
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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 1,2 ,3,4 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.	20SB-014-01	20SB-015-02	20SB-016-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	10-03-2020	10-03-2020	10-03-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin:** Firm has submitted copy of GMP certificate (No. JS20170734) issued by CFDA China. The certificate is valid till 25-12-2022. **Metformin:** Firm has submitted copy of GMP certificate (No. 14957/D1/4/2021) issued by Department of Food and Drugs Control Administration Government of Tamilnadu dated 10-01-2022. The certificate was valid till 31-12-2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of 500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 22-03-2019 specifying import of 3500kg metformin HCl. The invoice is signed 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.	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[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 316th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 316th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 316th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	ERTOZIN-M TABLET 2.5MG/1000mg
Batch No. of drug product	20SB-014-01 20SB-015-02 20SB-016-03
Case No.	727
Registration Board meeting	316th meeting of Registration Board held on 15th, 16th & 17th March, 2022

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Segluromet tablet.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Pharmaceutical Equivalence studies.
- Process validation protocol.
- Analytical method validation studies for drug product.

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.**		
15.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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 29158 dated 26-10-2021
	Details of fee submitted	Rs.75,000/- dated 12-10-2021
	The proposed proprietary name / brand name	**Erglif-M Tablets 7.5mg/1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin……....7.5mg Metformin HCl……..1000mg
	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Reference to Finished product specifications	Innovator Specification
	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	SEGLUROMET tablet 2.5mg/1000mg by Merck & Co. Inc, USA (USFDA Approved)
	For generic drugs (me-too status)	LOZGIL -M Tablets 2.5mg/1000mg by Genix Pharma Private Limited.
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Tablet section (General & Psycotropic) approved.
	Name and address of API manufacturer.	**Ertugliflozin:** Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd **Address:** Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China **Metformin HCL:** Abhilash Chemicals and Pharmaceuticals Private Limited, **Address:** 34/6A, Nayakkanpatti Village, Madurai North Taluk, Madurai. Pin Code – 625301. Tamil Nadu, 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)	Drug substances is tested at **Ertugliflozin** on in-house specifications & **Metformin HCL** on USP Specifications. 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Ertugliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ETG20161201, ETG20161202 & ETG20170101) **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: (MET/06/00546, MET/06/00547 & MET/06/00548)
	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 **SEGLUROMET tablet 7.5mg/1000mg (Batch no: S037722)** by Merck & Co. Inc by performing quality tests (Identification, Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is **SEGLUROMET tablet 7.5mg/1000mg (Batch no: S037722)** Merck & Co. Inc in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was in 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	**Ertugliflozin:** Shanghai Pharma Group Changzhou kony Pharmaceuticals Co., Ltd China Daixi street, Luoyang town, Wujin District, Changzhou, Jiangsu, China **Metformin hydrochloride:** Abhilash Chemicals and Pharmaceuticals Pvt. Ltd. 34/6A, Nayakanpatti village, Madurai North Taluk Madurai Tamilnadu India.
API Lot No.	**Ertugliflozin**: ETG20180901, **Metformin HCL**: MET/B/01/19030070
Description of Pack	Alu/alu blister

(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: 1,2 ,3,4 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.	20SB-026-01	20SB-027-02	20SB-028-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	25-03-2020	25-03-2020	25-03-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin:** Firm has submitted copy of GMP certificate (No. JS20170734) issued by CFDA China. The certificate is valid till 25-12-2022. **Metformin:** Firm has submitted copy of GMP certificate (No. 14957/D1/4/2021) issued by Department of Food and Drugs Control Administration Government of Tamilnadu dated 10-01-2022. The certificate was valid till 31-12-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of 500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 22-03-2019 specifying import of 3500kg metformin HCl. The invoice is signed 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.	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[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 316th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 316th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 316th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi

Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	ERTOZIN-M TABLET 7.5MG/1000mg
Batch No. of drug product	20SB-026-01 20SB-027-02 20SB-028-03
Case No.	722
Registration Board meeting	316th meeting of Registration Board held on 15th, 16th & 17th March, 2022

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Segluromet tablet.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Pharmaceutical Equivalence studies.
- Process validation protocol.
- Analytical method validation studies for drug product.

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.**

16.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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 29990 dated 03-11-2021
	Details of fee submitted	Rs.75,000/- dated 22-10-2021
	The proposed proprietary name / brand name	**Erglif-M 2.5mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin……....2.5mg Metformin HCl……..500mg
	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides

	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Reference to Finished product specifications	Innovator Specification
	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	SEGLUROMET tablet 2.5mg/500mg by Merck & Co. Inc, USA (USFDA Approved)
	For generic drugs (me-too status)	ERTUVIA-M Tablets 2.5mg/500mg by Ferozsons Laboratories Private limited.
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Tablet section (General & Psycotropic) approved.
	Name and address of API manufacturer.	**Ertugliflozin:** Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd **Address:** Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China **Metformin HCL:** Abhilash Chemicals and Pharmaceuticals Private Limited, **Address:** 34/6A, Nayakkanpatti Village, Madurai North Taluk, Madurai. Pin Code – 625301. Tamil Nadu, 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)	Drug substances is tested at **Ertugliflozin** on in-house specifications & **Metformin HCL** on USP Specifications. 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Ertugliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ETG20161201, ETG20161202 & ETG20170101) **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: (MET/06/00546, MET/06/00547 & MET/06/00548)
	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 **SEGLUROMET tablet 2.5mg/500mg** (Batch no: S037765) by Merck & Co. Inc by performing quality tests (Identification, Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is **SEGLUROMET tablet 2.5mg/500mg** Merck & Co. Inc in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was in 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	**Ertugliflozin:** Shanghai Pharma Group Changzhou kony Pharmaceuticals Co., Ltd China Daixi street, Luoyang town, Wujin District, Changzhou, Jiangsu, China **Metformin hydrochloride:** Abhilash Chemicals and Pharmaceuticals Pvt. Ltd. 34/6A, Nayakanpatti village, Madurai North Taluk Madurai Tamilnadu India.		
API Lot No.	**Ertugliflozin**: ETG20180901, **Metformin HCL**: MET/B/01/19030070		
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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 1,2 ,3,4 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.	20SB-008-01	20SB-009-02	20SB-010-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	03-03-2020	03-03-2020	03-03-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin:** Firm has submitted copy of GMP certificate (No. JS20170734) issued by CFDA China. The certificate is valid till 25-12-2022. **Metformin:** Firm has submitted copy of GMP certificate (No. 14957/D1/4/2021) issued by Department of Food and Drugs Control Administration Government of Tamilnadu dated 10-01-2022. The certificate was valid till 31-12-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of

		500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 22-03-2019 specifying import of 3500kg metformin HCl. The invoice is signed 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.	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[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 322nd meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 322nd meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 322nd meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	ERTOZIN-M TABLET 2.5mg/500mg
Batch No. of drug product	20SB-008-01 20SB-009-02 20SB-010-03
Case No.	19
Registration Board meeting	322nd meeting of Registration Board held on 8th & 10th November, 2022

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Segluromet tablet.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Pharmaceutical Equivalence studies.
- Process validation protocol.
- Analytical method validation studies for drug product.

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.**

17.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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 29159 dated 26-10-2021
	Details of fee submitted	Rs.75,000/- dated 12-10-2021
	The proposed proprietary name / brand name	**Erglif-M 7.5mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin ……..... 7.5mg Metformin HCl …….. 500mg
	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Reference to Finished product specifications	Innovator Specification
	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	SEGLUROMET tablet 7.5mg/500mg by Merck & Co. Inc, USA (USFDA Approved)
	For generic drugs (me-too status)	ERTUVIA-M Tablets 7.5mg/500mg by Ferozsons Laboratories Private limited.
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Tablet section (General & Psycotropic) approved.
	Name and address of API manufacturer.	**Ertugliflozin:** Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd **Address:** Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China **Metformin HCL:** Abhilash Chemicals and Pharmaceuticals Private Limited, **Address:** 34/6A, Nayakkanpatti Village, Madurai North Taluk, Madurai. Pin Code – 625301. Tamil Nadu, 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)	Drug substances is tested at **Ertugliflozin** on in-house specifications & **Metformin HCL** on USP Specifications. 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Ertugliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ETG20161201, ETG20161202 & ETG20170101) **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: (MET/06/00546, MET/06/00547 & MET/06/00548)
	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 **SEGLUROMET tablet 7.5mg/500mg** (Batch no: S037765) by Merck & Co. Inc by performing quality tests (Identification, Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is **SEGLUROMET tablet 7.5mg/500mg** Merck & Co. Inc in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was in 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	**Ertugliflozin:** Shanghai Pharma Group Changzhou kony Pharmaceuticals Co., Ltd China Daixi street, Luoyang town, Wujin District, Changzhou, Jiangsu, China **Metformin hydrochloride:** Abhilash Chemicals and Pharmaceuticals Pvt. Ltd. 34/6A, Nayakanpatti village, Madurai North Taluk Madurai Tamilnadu India.
API Lot No.	**Ertugliflozin**: ETG20180901, **Metformin HCL**: MET/B/01/19030070
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: 24 months Accelerated: 6 months			
Frequency	Accelerated: 1,2 ,3,4 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)			
Batch No.	20SB-020-01		20SB-021-03	20SB-022-03
Batch Size	1500 Tablets		1500 Tablets	1500 Tablets
Manufacturing Date	02-2020		02-2020	02-2020
Date of Initiation	16-03-2020		16-03-2020	16-03-2020
No. of Batches	03			
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)		Not applicable	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		**Ertugliflozin:** Firm has submitted copy of GMP certificate (No. JS20170734) issued by CFDA China. The certificate is valid till 25-12-2022. **Metformin:** Firm has submitted copy of GMP certificate (No. 14957/D1/4/2021) issued by Department of Food and Drugs Control Administration Government of Tamilnadu dated 10-01-2022. The certificate was valid till 31-12-2024.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		**Ertugliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of 500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. **Metformin:** Firm has submitted copy of commercial invoice cleared dated 22-03-2019 specifying import of 3500kg metformin HCl. The invoice is signed 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.		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[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 322nd meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 322nd meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 322nd meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	ERTOZIN-M TABLET 7.5mg/500mg

Batch No. of drug product	20SB-020-01 20SB-021-03 20SB-022-03
Case No.	18
Registration Board meeting	322nd meeting of Registration Board held on 8th & 10th November, 2022

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Seglurometet tablet.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Pharmaceutical Equivalence studies.
- Process validation protocol.
- Analytical method validation studies for drug product.

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.**

18.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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 32072 dated 23-11-2021
	Details of fee submitted	Rs.75,000/- dated 16-11-2021
	The proposed proprietary name / brand name	**Dactril Capsule 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Racecadotril ……. 100mg
	Pharmaceutical form of applied drug	White color powder filled in Maroon color body & cap of Hard Gelatin Capsule Size "2"
	Pharmacotherapeutic Group of (API)	Anti-diarrheal
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	10's
	Proposed unit price	As per PRC

	The status in reference regulatory authorities	Hidrasec Capsules by M/s Abbott Laboratories. Approved.
	For generic drugs (me-too status)	Hidrasec Capsules by M/s Abbott Laboratories. Approved.Reg no: 087518
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Sachet section approved.
	Name and address of API manufacturer.	M/s Symed labs limited. Unit-II, Plot No. 25/B, Phase-III, I.D.A, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri (Dist) – 500 055, 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)	Racecadotril is non-pharmacopeial. 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 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (RAC L009, RAC L010 & RAC L011)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, 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 **Hidrasec** (B#SX554) by ABBOTT by performing quality tests (Identification, Assay, Disintegration Dissolution) CDP has been performed against the same brand that is **Hidrasec** (B#SX554) by ABBOTT, in Acid media (0.1N HCl), acetate buffer 4.5 & Phosphate Buffer pH (6.8). The f2 value was in acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity, robustness and justification of system suitability
STABILITY STUDY DATA		

Manufacturer of API		Symed Labs Limited		
API Lot No.		2KA0261119		
Description of Pack (Container closure system)		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: 6 months Accelerated: 6 months		
Frequency		Accelerated: 1,2,3,4 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.		20SB(A)-133-01	20SB(A)-134-02	20SB(A)-135-03
Batch Size		1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date		08-2020	08-2020	08-2020
Date of Initiation		20-08-2020	20-08-2020	20-08-2020
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable		
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 17/12/2021		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase invoice No.EXP/1334 dated 19/02/2020 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:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 324th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 324th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 324th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Racetril capsule 100mg
Batch No. of drug product	20SB-133-01 20SB-134-02 20SB-135-03
Case No.	1318
Registration Board meeting	324th meeting of Registration Board held on 24th to 26th January, 2024

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Hidrasec capsule.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation.
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- Pharmaceutical equivalence studies
- QOS.
- Process validation protocol.
- Analytical method validation studies for drug product.

Sr.#	Section#	Observation	Response
1.	**1.6.5**	Valid GMP certificate of drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate in the name of M/s Symed Labs Limited., Plot No. 25/B, Phase-III, IDA, Jeedimetla Village, Quthbullapur Mandal, Medchal - Malkajgiri District, Pincode 500005, Telangana State, India., issued by Deputy Director and Certifying Authority Drugs Control Administration Telangana State India valid upto 24-04-2023.
2.	**3.2.S.5**	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability	• Submitted.

		(method precision) performed by the Drug Product manufacturer shall be submitted.	
3.	**3.2.P.5**	• Justification shall be submitted for not including dissolution test in the drug product specifications	• Firm has referred to the submitted batch analysis certificates and stability studies wherein dissolution test has been performed.
4.	**3.2.P.8**	• Documents confirming import of API shall be submitted, attested from DRAP I&E office.	• Firm has submitted readable copy of invoice No. EXP/1334 dated 19-02-2020 for import of 0.85kg of Racecadotril (Batch#2KA0261119) in name of M/s Genix Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 17-03-2020.

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.**

19.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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**
	Evidence of required manufacturing facility	Sachet general section approval confirmed form the copy of renewal of DML letter submitted dated 20-09-2021.
	Dy. No. and date of submission	Dy.No 30932 dated 11-11-2021
	Details of fee submitted	Rs.75,000/- dated 25-10-2021
	The proposed proprietary name / brand name	**Dactril sachet 30mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Racecadotril……..30mg
	Pharmaceutical form of applied drug	Free flowing white granules
	Pharmacotherapeutic Group of (API)	Anti-diarrheal
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	16's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Hidrasec by M/s Abbott laboratories approved by MHRA of UK
	For generic drugs (me-too status)	Hidrasec by M/s Abbott laboratories. Approved.Reg no: 087082
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Sachet section approved.
	Name and address of API manufacturer.	M/s Symed labs limited. Unit-II, Plot No. 25/B, Phase-III, I.D.A, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri (Dist) – 500 055, 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)	Racecadotril is non-pharmacopeial. 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 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (RAC L009, RAC L010 & RAC L011)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, 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 **Hidrasec** (B#SXE2242) by ABBOTT by performing quality tests (Identification, Assay, Disintegration Dissolution) CDP is not applicable.

	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity, robustness and justification of system suitability		
STABILITY STUDY DATA				
Manufacturer of API		M/s Symed labs limited. Unit-II, Plot No. 25/B, Phase-III, I.D.A, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri (Dist) – 500 055, Telangana, INDIA		
API Lot No.		2KA0261119		
Description of Pack (Container closure system)		Sachet 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: 3 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.		20SB(A)-028-01	20SB(A)-029-02	20SB(A)-030-03
Batch Size		1500 Sachets	1500 Sachets	1500 Sachets
Manufacturing Date		12-2020	12-2020	12-2020
Date of Initiation		04-01-2021	04-01-2021	04-01-2021
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.	Copy of GMP certificate valid till 17/12/2021		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase invoice No.EXP/1334 dated 19/02/2020 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[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 324th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 324th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 324th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi

Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Racetril sachet 30mg
Batch No. of drug product	20SB(A)-028-01 20SB(A)-029-02 20SB(A)-030-03
Case No.	1317
Registration Board meeting	324th meeting of Registration Board held on 24th to 26th January, 2024

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of Pharmaceutical equivalence data against the reference product of Hidrasec sachet.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Process validation protocol.
- Analytical method validation studies for drug product.

20.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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**
	Evidence of required manufacturing facility	Sachet general section approval confirmed form the copy of renewal of DML letter submitted dated 20-09-2021.
	Dy. No. and date of submission	Dy.No 30773 dated 10-11-2021
	Details of fee submitted	Rs.75,000/- dated 25-10-2021
	The proposed proprietary name / brand name	**Dactril sachet 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Racecadotril……..10mg
	Pharmaceutical form of applied drug	Free flowing white granules
	Pharmacotherapeutic Group of (API)	Anti-diarrheal
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	16's
	Proposed unit price	As per PRC

	The status in reference regulatory authorities	Hidrasec by M/s Abbott laboratories approved by MHRA of UK
	For generic drugs (me-too status)	Hidrasec by M/s Abbott laboratories. Approved.Reg no: 087082
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Sachet section approved.
	Name and address of API manufacturer.	M/s Symed labs limited. Unit-II, Plot No. 25/B, Phase-III, I.D.A, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri (Dist) – 500 055, 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)	Racecadotril is non-pharmacopeial. 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 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (RAC L009, RAC L010 & RAC L011)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, 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 **Hidrasec** (B#SXN635) by ABBOTT by performing quality tests (Identification, Assay, Disintegration Dissolution) CDP is not applicable.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity, robustness and justification of system suitability

STABILITY STUDY DATA	
Manufacturer of API	M/s Symed labs limited. Unit-II, Plot No. 25/B, Phase-III, I.D.A, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri (Dist) – 500 055, Telangana, INDIA
API Lot No.	2KA0261119

Description of Pack (Container closure system)		Sachet 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: 3 & 6 (Months) Real Time: 3, 6, 9 ,12,18 & 24 (Months)		
Batch No.		20SB(A)-025-01	20SB(A)-026-02	20SB(A)-027-03
Batch Size		1500 Sachets	1500 Sachets	1500 Sachets
Manufacturing Date		12-2020	12-2020	12-2020
Date of Initiation		04-01-2021	04-01-2021	04-01-2021
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.	Copy of GMP certificate valid till 17/12/2021		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase invoice No.EXP/1334 dated 19/02/2020 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:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 324th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 324th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 324th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Racetril sachet 10mg
Batch No. of drug product	20SB(A)-025-01 20SB(A)-026-02 20SB(A)-027-03
Case No.	1316
Registration Board meeting	324th meeting of Registration Board held on 24th to 26th January, 2024

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of Pharmaceutical equivalence data against the reference product of Hidrasec sachet.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Process validation protocol.
- Analytical method validation studies for drug product.

Sr.#	Section#	Observation	Response
5.	**1.6.5**	Valid GMP certificate of drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate in the name of M/s Symed Labs Limited., Plot No. 25/B, Phase-III, IDA, Jeedimetla Village, Quthbullapur Mandal, Medchal - Malkajgiri District, Pincode 500005, Telangana State, India., issued by Deputy Director and Certifying Authority Drugs Control Administration Telangana State India valid upto 24-04-2023.
6.	**3.2.S.5**	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product	• Submitted.

		manufacturer shall be submitted.	
7.	**3.2.P.2.2.1**	• Submit justification of not performing tests of dissolution in Pharmaceutical equivalence studies. • Comparative dissolution profile study shall be submitted against the innovator drug product.	• Firm has submitted revised Pharmaceutical equivalence studies including dissolution test and CDP studies against the Hidrasec sachet for both 10mg & 30mg strength.
8.	**3.2.P.5**	• Justification shall be submitted for not including dissolution test in the drug product specifications	• Firm has submitted revised drug product specifications including dissolution test.
9.	**3.2.P.8**	• Justification shall be submitted for not performing tests of dissolution during stability studies. • Documents confirming import of API shall be submitted, attested from DRAP I&E office.	• Firm has submitted performance of recent time point of long term stability studies including performance of dissolution test. • Firm has submitted readable copy of invoice No. EXP/1334 dated 19-02-2020 for import of 0.85kg of Racecadotril (Batch#2KA0261119) in name of M/s Genix Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 17-03-2020.

Decision: Registration Board approved the applications of Dactril sachet 10mg & Dactril sachet 30mg with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for each strength for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **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.**

21.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	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 24846 dated 08-09-2021
	Details of fee submitted	Rs.75,000/- dated 14-06-2021
	The proposed proprietary name / brand name	**Dorip Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Doripenem Monohydrate eq. to Doripenem …500mg
	Pharmaceutical form of applied drug	A white to slightly yellowish off-white crystalline powder.
	Pharmacotherapeutic Group of (API)	Anti-bacterial
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Doribax Injection by Shionogi & Co. Ltd. Japan Approved.
	For generic drugs (me-too status)	Dorinem Injection by M/s ICI Pakistan Reg no: 098825
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Dry powder Injection (General antibiotic) approved.
	Name and address of API manufacturer.	Kopran Research Laboratories Limited. Parijat House, Dr. E. Moses Road, Worli, Mumbai-400018, 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)	Doripenem is non-pharmacopeial. 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 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (DPIV/P1503001, DPIV/P1503002 & DPIV/P1503003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative	Pharmaceutical Equivalence have been established

	dissolution profile	against the brand leader that is **Dorinem Injection** (B#0E0457) by ICI Pakistan by performing quality tests (Appearance, Identification, pH, Assay,)
	Analytical method validation/verification of product	Method validation studies have been submitted including specificity, linearity, accuracy, precision, repeatability, intermediate precision, robustness, range and justification of system suitability

STABILITY STUDY DATA

Manufacturer of API	Kopran research laboratories Ltd.		
API Lot No.	DPIV/P1901002		
Description of Pack (Container closure system)	Aluminium canister		
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, 9 ,12,18 & 24 (Months)		
Batch No.	001I050	002I050	003I050
Batch Size	5657 Vials	5657 Vials	5657 Vials
Manufacturing Date	07-2019	09-2019	11-2019
Date of Initiation	19-08-2019	01-10-2019	31-12-2019
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.	Copy of GMP certificate valid till 19/10/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase invoice No. BEXP-1819-384 dated 15.03.2019 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[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 277th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 277th meeting on Form 5D, based on the stability data verified by On-site inspection. The details of the already considered product in 277th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Ronim Injection 500mg
Batch No. of drug product	TR001 TR002 TR003
Case No.	900
Registration Board meeting	277th meeting of Registration Board held on 27-29th December, 2017

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 277th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative analysis against the reference product of DORIBAX Injection.
  - Complete batch manufacturing record of three stability batches.
  - Finished drug product analytical method validation
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- QOS.
- Process validation protocol.
- Analytical method validation studies for drug product.

Previously the applied formulation was developed and approved with innovator's specifications, whereas subsequently it has been identified that JP monograph is now available for the "Doripenem for injection."

Decision: Approved with JP specifications. 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 07-05-2021, before issuance of registration letter.

- **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.**

22.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial 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 2386 dated 25-01-2023
	Details of fee submitted	PKR 75,000/-: dated 08-12-2022
	The proposed proprietary name / brand name	**Trivesta-M XR 12.5/2.5/1000mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Empagliflozin (Immediate Release) …. 12.5mg Linagliptin (Immediate Release) ...…… 2.5mg Metformin HCl (Extended Release) ….1000mg
	Pharmaceutical form of applied drug	Grey colored, oblong shaped Film coated Extended Release Tablet.
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (Type-II)
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	2×7's, 4×7's, 2×5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR 12.5/2.5/1000mg Tablet by Boehringer Ingelheim International GmbH (USFDA approved)
	For generic drugs (me-too status)	Not Available
	GMP status of the Finished product manufacturer	New license granted on 14/09/2022 Tablet (General, Narcotics & Psychotropic) section 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. **Linagliptin:** M/s Lee Pharma Limited, Survey No. 10/G-1, Gadda Potharam (Village) Jinnaram (Mandal), Sangareddy (District) Telangana, 502319, INDIA. **Metformin HCl:** M/S Ipca Laboratories Limited, H-4, M.LD.C., Waluj, Aurangabad (Maharashtra) Pin: 431 136, 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 monographs of Empagliflozin, Linagliptin are not available in any official Pharmacopoeia & Official monograph of Metformin HCl is available in British Pharmacopoeia as well as in United States Pharmacopoeia. The API Manufacturer of Metformin HCl used B.P. Specifications & Manufacturers of Empagliflozin and Linagliptin used In-house Specifications. The firm as submitted both APIs details 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 both drug substances.
	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: (20160606, 20161017, 20161219) **Linagliptin:** 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: (LI0316005, LI0316006, LI0316007) **Metformin HCl:** 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: (9002ML2RMl, 9003ML2RMl, 9004ML2RMl)
	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 TRIJARDY XR 12.5/2.5/1000mg Tablets by Boehringer Ingelheim International GmbH by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is TRIJARDY XR 12.5/2.5/1000mg Tablet by Boehringer Ingelheim International GmbH in Acid media (0.1N HCl) & Buffer (pH 4.5 & 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	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Linagliptin:** M/s Lee Pharma Limited, Survey No. 10/G-1, Gadda Potharam (Village) Jinnaram (Mandal), Sangareddy (District) Telangana, 502319, INDIA.	

	Metformin HCl: M/S Ipca Laboratories Limited, H-4, M.L.D.C., Waluj, Aurangabad (Maharashtra) Pin: 431 136, India.		
API Lot No.	**Empagliflozin:** H-E-20210826-D02-E06-01 **Linagliptin:** LIFP21012 **Metformin HCl:** 21296ML2ARMI		
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.	NPD/PR22-023/T1/S1	NPD/PR22-023/T1/S2	NPD/PR22-023/T1/S3
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	26-02-2022	26-02-2022	26-02-2022
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 also submitted a request to DRAP that as per decision of 312 DRB Meeting, they have submitted all the required documents mentioned in minutes. So, Firm requested to please interimly extend the exemption from onsite inspection to 05 years for all dosage forms on behalf of submitted required data and inspection done on 21st May 2019 and wherein the registration of that product was accorded in 292 DRB meeting.
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. LN210014 issued by People's Republic of China Drug Administration, China. valid till 25/05/2024. **Linagliptin:** Copy of GMP certificate No. L. Dis.No: 86097/TS/2022 issued by DRUGS CONTROL ADMINISTRATION, Government of Telangana valid till 08/05/2023. **Metformin HCl:** Copy of GMP certificate No. No.: NEW-WHO-GMP/CERT/AD/104179/2021/11/37725 issued by Food & D rugs A administration valid till 07/10/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Copy of Invoice HN211026-J dated 04-11-2021 is submitted wherein the permission to import Empagliflozin (10Kg) for the purpose of test/analysis and stability studies is granted vide No. 16617/2021-DRAP dated 09-11-2021. **Linagliptin:**

		Copy of Invoice 1269/LP/2021-22 dated 07-10-2021 is submitted wherein the permission to import Linagliptin (4Kg) for the purpose of test/analysis and stability studies is granted vide No. 15358/2021-DRAP dated 13-10-2021. **Metformin HCl:** Copy of Invoice SMP2122/1630075 dated 25-08-2021 is submitted wherein the permission to import Linagliptin for the purpose of test/analysis and stability studies is granted vide No. 13246/2021-DRAP dated 02-09-2021.
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:

Section#	Observations	Firm's response
1.6.5	Copy of Valid GMP certificate for M/s Fuxin Long Rui, issued by relevant regulatory authority shall be submitted.	
	Empagliflozin	
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.	
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.	
3.2.S.4.4	• Submitted COA from M/s Wilshire, mentions different batch number from that declared on the COA from drug substance manufacturer. • Submitted COA from M/s Wilshire mentions test of "Water content" whereas COA from Drug substance manufacturer specifies test of "Loss on drying". • In contrary to the innovator drug product literature from the US FDA & EMA, the section 3.2.S.1.3 & submitted COA of drug substance from M/s Wilshire declare the solubility in water as "practically insoluble". Justification shall be submitted in this regard. • Submitted COA of drug substance from M/s Wilshire declare the results for test of optical rotation which is not included in the drug substance specifications and COA form drug substance manufacturer.	
3.2.S.5	Submitted COA of working standard declare the expiry date as 18-04-2018 whereas drug substance analysis has been performed subsequent to this date. Justification shall be submitted in this regard.	
	Metformin HCl	

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.	
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.	
3.2.S.5	Submitted COA of working standard declare the expiry date as June, 2019 whereas drug substance analysis has been performed subsequent to this date. Justification shall be submitted in this regard.	
	Linagliptin	
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. • Justification shall be submitted for the proposed limits of "NMT 1.0%" for the test of "Enantiomer content (S-Isomer content) by the drug substance manufacturer. • As per innovator drug product literature review the "S-isomer" is controlled as an impurity. While referring to the declared limit from drug substance manufacturer for "S-Isomer", the limit for the "Total impurities" as "NMT 1.0%" shall be justified.	
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 method of analysis from drug substance manufacturer for the test of "Enantiomeric purity declares use of tests sample for both standard and sample solution. Justification shall be submitted din this regard.	
3.2.S.4.4	• Submitted COA from M/s Wilshire mentions test of "Water content" whereas COA from Drug substance manufacturer specifies test of "Loss on drying". • Submitted COA of drug substance from both drug product and drug substance manufacturer does not confirm "Enantiomeric purity". Justification shall be submitted in this regard. • Submitted COA of drug substance from M/s Wilshire declare the results for test of residue on ignition which is not included in the drug substance specifications and COA form drug substance manufacturer.	
3.2.S.5	Submitted COA of working standard of Linagliptin & S-Isomer declare the expiry date as November, 2019 & December, 2018 respectively, whereas drug substance analysis has been performed subsequent to this date. Justification shall be submitted in this regard.	
3.2.P.1	• Justification shall be submitted for proposed Quantity/tablet of Empagliflozin and Linagliptin against the label claim.	
3.2.P.2	• Justification shall be submitted for proposed quantity of Arginine in the formulation. • Submit the image/picture/snapshot of the innovator/reference/comparator pack	

	against which Pharmaceutical equivalence / Comparative Dissolution Profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator/reference/comparator product. • Dissolution specifications mentioned in Pharmaceutical equivalence studies for Empagliflozin are different from that declared in section 3.2. P.5.1. • Justification shall be submitted for not performing tests of water content, uniformity of content, microbial purity and arginine content in Pharmaceutical equivalence studies as recommended by the innovator product literature review from reference regulatory authorities. • Details shall be submitted for the dissolution parameters applied for the performance of CDP studies. • Complete analytical record shall be submitted for the performance of the Pharmaceutical equivalence & CDP studies. • The results presented for the dissolution profile of innovator product i.e., Trijardy XR tablet are contradictory to those reported in the review literature f innovator product from the reference regulatory authority. Justification shall be submitted in this regard.	
3.2.P.3.4	• In contrary to the recommendations of innovator product literature, "particle size" of Empagliflozin & Linagliptin has not been identified as Critical Quality Attribute.	
3.2.P.5.1	• Justification shall be submitted for not including tests of water content, microbial purity and arginine content in drug product specifications as recommended by the innovator product literature review from reference regulatory authorities.	
3.2.P.5.3	• Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". • Concentrations (in mg/ml) applied for the performance of Linearity and Accuracy parameter shall be justified against the standard and sample concentrations of	

	each drug substance declare din the drug product analytical procedure for Assay test. • Limits of 90-110% for the performance of accuracy parameter shall be justified.	
3.2.P.5.4	The copies of complete analysis of trial batches shall be provided.	
3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.8.3	• Justification shall be submitted for not including tests of water content, microbial purity and arginine content in stability studies. • Peak integration and run time is not evident from the submitted chromatograms. • Complete raw data sheets for the performance of Assay & Dissolution test during stability studies shall be submitted, wherein details of standard weight, sample weight, dilution preparation and calculation formula applied for the results shall have been included. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
2.3.R	• Justification shall be submitted for dispensed quantity of Empagliflozin & Linagliptin alongwith 10% overage for formulation of trial batches. • Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation. • Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin & Linagliptin at in process stage of active coating. • Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin and Linagliptin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing. • Minimum handling capacity of the equipment used in the manufacturing of trial batches shall be submitted.	

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

Agenda of Evaluator PEC-III

Case No. 03 Registration applications of Form-5 cases

a) New cases

23.	**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	Obsilate Tablet 500mg

	Composition	Each Film Coated Tablet Contains: Calcium Dobesilate…500mg
	Diary No. Date of R& I & fee	Dy No. 16077: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antivaricose Therapy
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house 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	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	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 applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	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 adopted by the Registration Board in its 275th meeting.**	
24.	**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	Obfylin Syrup 100mg/5ml
	Composition	Each 5ml of Syrup Contains: Doxofylline…100mg
	Diary No. Date of R& I & fee	Dy No. 16070: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other Systemic Drugs For Obstructive Airway Diseases
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy Approved
	Me-too status	Unifyline Syrup by Platinum
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
25.	**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	Obzin Syrup 20mg/5ml
	Composition	Each 5ml Contains: Zinc (as Sulphate monohydrate)…20mg
	Diary No. Date of R& I & fee	Dy No. 16078: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other Mineral Supplements
	Type of Form	Form 5
	Finished Product Specification	Ph. Int.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in any RRA or NEML, Paediatric zinc sulfate oral solution monograph in international pharmacopoeia under the heading of Additional information specifies that "*Available strengths: 10 mg or 20 mg of zinc per 5 mL*"
	Me-too status	Zincbar Syrup by MBL Pharma
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022

	Remarks of the Evaluator[3].	
	Decision: Approved.	
26.	**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	Obsemide Tablet 20mg
	Composition	Each Tablet Contains: Furosemide…20mg
	Diary No. Date of R& I & fee	Dy No. 16075: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Uriside tablet by Nabiqasim
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	
	Decision: Approved.	
27.	**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	Obsemidel Tablet 40mg
	Composition	Each Tablet Contains: Furosemide…40mg
	Diary No. Date of R& I & fee	Dy No. 16076: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Uriside tablet by Nabiqasim
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	
	Decision: Approved.	
28.	**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	Clazine Tablet 30mg
	Composition	Each Modified Release Tablet Contains: Gliclazide …30mg
	Diary No. Date of R& I & fee	Dy No. 16066: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house 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	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	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 applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	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 adopted by the Registration Board in its 275th meeting.**	
29.	**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	Clazine Tablet 60mg
	Composition	Each Modified Release Tablet Contains: Gliclazide …60mg
	Diary No. Date of R& I & fee	Dy No. 16067: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house 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	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	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 applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	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 adopted by the Registration Board in its 275th meeting.**	
30.	**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	Obicetam Syrup 1g/5ml
	Composition	Each 5ml of Syrup Contains: Piracetam…1g
	Diary No. Date of R& I & fee	Dy No. 16071: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved.
	Me-too status	Nootropil Syrup by AGP
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
31.	**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	Oxamin Tablet 550mg
	Composition	Each Tablet Contains: Rifaximin…550mg
	Diary No. Date of R& I & fee	Dy No. 16080: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Axibol Tablet by Genetics Pharma
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin…550mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rifaximin…550mg** • **Firm shall submit 7,500/- fee for revision of formulation from un-coated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
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	Obivarox Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…10mg
	Diary No. Date of R& I & fee	Dy No. 16064: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Direct factor Xa inhibitors
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Taboxa Tablet by Novamed
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	
	Decision: Approved.	
33.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Osteomend 70mg Tablet
	Composition	Each Tablet Contains: Alendronate As Sodium…70mg
	Diary No. Date of R& I & fee	Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Alendra 70mg Tablet by Miracle Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Alendronic acid (as sodium trihydrate) …70mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Alendronic acid (as sodium trihydrate) …70mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
34.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**

	Brand Name +Dosage Form + Strength	Goutcure 80mg Tablet
	Composition	Each Tablet Contains: Febuxostat…80mg
	Diary No. Date of R& I & fee	Dy No. 13658: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-gout Preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zurig Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
35.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Itoride 150mg Tablet
	Composition	Each Tablet Contains: Itopride As HCl…150mg
	Diary No. Date of R& I & fee	Dy No. 13659: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiemetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ganaton OD Tablet by Abbott
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • 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.	
36.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Itracone 100mg Capsule
	Composition	Each Capsule Contains: Itraconazole…100mg
	Diary No. Date of R& I & fee	Dy No. 13661: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antimycotics For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Icon Capsule by Ferozesons
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).

		• Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Capsule Contains: Itraconazole (as IR pellets)…100mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Itraconazole (as IR pellets)…100mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
37.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Linzorin 400mg Tablet
	Composition	Each Tablet Contains: Linezolid…400mg
	Diary No. Date of R& I & fee	Dy No. 13663: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nezkil Tablet by S.J&G Fazul Ellahie
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Linezolid…400mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Linezolid…400mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
38.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Linzorin 600mg Tablet
	Composition	Each Tablet Contains: Linezolid…600mg
	Diary No. Date of R& I & fee	Dy No. 13664: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nezkil Tablet by S.J&G Fazul Ellahie
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Linezolid…600mg

	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Linezolid…600mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
39.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Ondon 8mg Tablet
	Composition	Each Tablet Contains: Ondansetron…8mg
	Diary No. Date of R& I & fee	Dy No. 13660: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Danset Tablet by CCL
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Ondansetron (as hydrochloride dihydrate)…8mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Ondansetron (as hydrochloride dihydrate)…8mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
40.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Hi-Slim 120mg Tablet
	Composition	Each Tablet Contains: Orlistat…120mg
	Diary No. Date of R& I & fee	Dy No. 13665: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiobesity
	Type of Form	Form 5
	Finished Product Specification	USP
	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	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • 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.
	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 adopted by the Registration Board in its 275th meeting.**	
41.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**

	Brand Name +Dosage Form + Strength	Tamlusin 0.4mg Capsule
	Composition	Each Capsule Contains: Tamsulosin Hcl Sustained Release Pellets Eq. To Tamsulosin Hcl…0.4mg
	Diary No. Date of R& I & fee	Dy No. 13655: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Maxflow Capsule by CCL
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Capsule Contains: Tamsulosin HCl Modified Release Pellets Eq To Tamsulosin……0.4mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Tamsulosin HCl Modified Release Pellets Eq To Tamsulosin……0.4mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
42.	**Name and address of manufacturer / Applicant**	**M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Seta Tablet 8mg
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…8mg
	Diary No. Date of R& I & fee	Dy No. 16299: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	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[3].	
	Decision: Approved.	
43.	**Name and address of manufacturer / Applicant**	**M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Seta Tablet 16mg
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…16mg
	Diary No. Date of R& I & fee	Dy No. 16296: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	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[3].	
	Decision: Approved.	
44.	**Name and address of manufacturer / Applicant**	**M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Seta Tablet 24mg
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…24mg
	Diary No. Date of R& I & fee	Dy No. 16297: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	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[3].	
	Decision: Approved.	
45.	**Name and address of manufacturer / Applicant**	**M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Quetil Tablet 25mg
	Composition	Each Tablet Contains: Quetiapine Fumarate…25mg
	Diary No. Date of R& I & fee	Dy No. 16294: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Q-Par Tablet by Helix
	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[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Quetiapine (as fumarate)…25mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Quetiapine (as fumarate) ….. 25mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
46.	**Name and address of manufacturer / Applicant**	**M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, KPK**
	Brand Name +Dosage Form + Strength	Deslor 0.5mg/ml Syrup
	Composition	Each 5ml Syrup Contains: Desloratadine…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16180: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dezika Syrup by Islam Pharma
	GMP status	
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
47.	**Name and address of manufacturer / Applicant**	**M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, KPK**
	Brand Name +Dosage Form + Strength	Deslor 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 16179: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Destina Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
48.	**Name and address of manufacturer / Applicant**	**M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, KPK**
	Brand Name +Dosage Form + Strength	Articerin 50mg Capsule
	Composition	Each Capsule Contains: Diacerein…50mg
	Diary No. Date of R& I & fee	Dy No. 16181: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diacerein Biogaran 50 mg, capsule ANSM Approved.
	Me-too status	Diora Capsule by Getz
	GMP status	
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
49.	**Name and address of manufacturer / Applicant**	**M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, KPK**
	Brand Name +Dosage Form + Strength	Thiosid 4mg Capsule
	Composition	Each Capsule Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy No. 16178: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg, capsule ANSM France Approved
	Me-too status	Thiolax Capsule by S.J&G Fazul Ellahie
	GMP status	
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
50.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Cordium V Tablets 5/80mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Dy No. 13626: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	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[3].	
	Decision: Approved.	
51.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	C Vit Tablet 500mg
	Composition	Each Chewable Tablet Contains: Ascorbic Acid…500mg
	Diary No. Date of R& I & fee	Dy No. 16342: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antioxidant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Kinuca Chewable 500mg Tablet by Winthrox
	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[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 adopted by the Registration Board in its 275th meeting.	
52.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Urifin Tablet 40mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…40mg
	Diary No. Date of R& I & fee	Dy No. 13627: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-gout Preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zurig Tablet by Getz
	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[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
53.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Urifin Tablet 80mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…80mg
	Diary No. Date of R& I & fee	Dy No. 13628: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-gout Preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zurig Tablet by Getz
	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[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
54.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Onset Syrup 4mg/5ml
	Composition	Each 5ml Contains: Ondansetron Hcl Dihydrate Eq To Ondanserton…4mg
	Diary No. Date of R& I & fee	Dy No. 16340: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ondasave oral solution by Medisave
	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[3].	
	Decision: Approved.	
55.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ripzole Tablet 10mg
	Composition	Each Tablet Contains: Aripiprazole…10mg
	Diary No. Date of R& I & fee	Dy No. 16091: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Aripaze Tablet by Global

	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Capsule Contains: Each Film Coated Tablet Contains: Aripiprazole…10mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Aripiprazole…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
56.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Recloza 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Cyclobenzaprine HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 16102: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	FLEXERIL (5mg, 10mg) film coated tablets USFDA Approved and Discontinued with reason that "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons"
	Me-too status	Cybem Tablet by Sami Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
57.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Restero 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Dydrogesterone…10mg
	Diary No. Date of R& I & fee	Dy No. 16104: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Progestogens
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duphaston 10mg film-coated tablets by M/s Mylan IRE Healthcare Limited (Ireland Approved)
	Me-too status	Dydrstone 10mg Tablet by Pharmasol
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section from Licensing Division • Clarification about the type of isomer of Dydrogesterone that will be used in formulation
	Decision: Deferred for following submissions: • **Evidence of required manufacturing facility / section from Licensing Division** • **Clarification about the type of isomer of Dydrogesterone that will be used in formulation** • **Latest GMP inspection report conducted within a period of last three years.**	

58.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Rasta 10/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Ezetimibe…10mg Simvastatin…10mg
	Diary No. Date of R& I & fee	Dy No. 16098: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Simvax Plus Tablet by Evolution pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Ezetimibe…10mg Simvastatin…10mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Tablet Contains:** **Ezetimibe…10mg** **Simvastatin…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
59.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Repride 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride Hcl…50mg
	Diary No. Date of R& I & fee	Dy No. 16092: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiemetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Ganaton Tablet by Abbott
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
60.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ramine 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Lamotrigine…25mg
	Diary No. Date of R& I & fee	Dy No. 16106: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lamictal Tablet by GSK
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Lamotrigine…25mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Lamotrigine…25mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
61.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ramine 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lamotrigine…50mg
	Diary No. Date of R& I & fee	Dy No. 16107: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lamictal Tablet by GSK
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Lamotrigine…50mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Lamotrigine…50mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
62.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Rantin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine As Hcl…10mg
	Diary No. Date of R& I & fee	Dy No. 16087: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Afdol Tablet by AGP
	GMP status	

	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Memantine HCl…10mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Memantine HCl…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
63.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Rebol 10mg Tablet
	Composition	Each Tablet Contains: Nebivolol as HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 16090: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nebil Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
64.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Reprazo 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Rabeprazole Sodium…20mg
	Diary No. Date of R& I & fee	Dy No. 16100: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Protorib Tablet by Helix
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
65.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Relsar 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R& I & fee	Dy No. 16093: 07-03-2019

		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
66.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Relsar Tablet 40mg
	Composition	Each Tablet Contains: Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy No. 16095: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
67.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Relsar 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg
	Diary No. Date of R& I & fee	Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
68.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Amlosar 5/80mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Dy No. 16256: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
69.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Duloxine 30mg Capsule
	Composition	Each Capsule Contains: Duloxetine as HCl…30mg
	Diary No. Date of R& I & fee	Dy No. 16253: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…30mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…30mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
70.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Duloxine 60mg Capsule
	Composition	Each Capsule Contains: Duloxetine as HCl Enteric Coated Pellets…60mg
	Diary No. Date of R& I & fee	Dy No. 16243: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

		• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…60mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…60mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
71.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Racoxib 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib …60mg
	Diary No. Date of R& I & fee	Dy No. 16250: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiinflammatory and Antirheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Etoxib Tablet by Hiranis
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
72.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Ropride 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride HCl…50mg
	Diary No. Date of R& I & fee	Dy No. 16252: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiemetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Ganaton Tablet by Abbott
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
73.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**

	Brand Name +Dosage Form + Strength	Rasomide 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Dy No. 16245: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
74.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Rasomide 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Dy No. 16246: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
75.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Zapitine Capsule 6/25mg
	Composition	Each Capsule Contains: Olanzapine…6mg Fluoxetine As Hcl…25mg
	Diary No. Date of R& I & fee	Dy No. 16249: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
76.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Lipformin 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Sitagliptin as Phospate Monohydrate…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 16248: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Treivamet Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
77.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Fenarcin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…5mg
	Diary No. Date of R& I & fee	Dy No. 16258: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Solif Tablet by Global
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
78.	**Name and address of manufacturer / Applicant**	**M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat,Islamabad**
	Brand Name +Dosage Form + Strength	Omex 40mg Capsule
	Composition	Each Capsule Contains: Omeprazole…40mg
	Diary No. Date of R& I & fee	Dy No. 15078: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Risek capsule by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following:

		Each Capsule Contains: Omeprazole (as enteric coated pellets)…40mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Omeprazole (as enteric coated pellets)…40mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
79.	**Name and address of manufacturer / Applicant**	**M/s Relizon Pharmaceuticals Plot No. 118, Sunder Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Reldic 100mg Tablet
	Composition	Each Tablet Contains: Diclofenac Sodium…100mg
	Diary No. Date of R& I & fee	Dy No. 15503: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diclomax SR Tablet by Quaper Pharma
	GMP status	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 was GMP compliant on the day of inspection.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Extended Release Tablet Contains: Diclofenac Sodium…100mg
	Decision: Approved with following label claim: **Each Extended Release Tablet Contains:** **Diclofenac Sodium…100mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
80.	**Name and address of manufacturer / Applicant**	**M/s Relizon Pharmaceuticals Plot No. 118, Sunder Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Ebastizon Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Dy No. 15500: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Netherland Approved.
	Me-too status	Kestine Tablet by Highnoon
	GMP status	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 was GMP compliant on the day of inspection.
	Remarks of the Evaluator[3].	•
	Decision: Approved with JP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
81.	**Name and address of manufacturer / Applicant**	**M/s Relizon Pharmaceuticals Plot No. 118, Sunder Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Metrozone Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Metronidazole…400mg
	Diary No. Date of R& I & fee	Dy No. 15501: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Imidazole 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.	MHRA Approved
	Me-too status	Flagyl Tablet by Sanofi Aventis
	GMP status	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 was GMP compliant on the day of inspection.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
82.	**Name and address of manufacturer / Applicant**	**M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore.**
	Brand Name +Dosage Form + Strength	Pedigerm Oral Suspension
	Composition	Each 5ml Contains: Bacillus Clausii…2 Billion
	Diary No. Date of R& I & fee	Dy No. 16456: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Probiotics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Enterogermina oral suspension by Sanofi Aventis
	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[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • The applied product is a probiotic, which is defined as health and OTC Products (non-drugs) as per DRAP Act 2012 and also defined under S.R.O. 412(I)/2014 while you have applied as a pharmaceutical drug product. Clarification is required in this regard.
	Decision: Registration Board decided to reject the application since the applied product is a probiotic which is defined as health and OTC Products (non-drugs) as per DRAP Act 2012 and also defined under S.R.O. 412(I)/2014.	
83.	**Name and address of manufacturer / Applicant**	**M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore.**
	Brand Name +Dosage Form + Strength	Zinstill Syrup
	Composition	Each 5ml Solution Contains: Zinc Sulphate Monohydrate…20mg
	Diary No. Date of R& I & fee	Dy No. 16460: 07-03-2019

		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other Mineral Supplements
	Type of Form	Form 5
	Finished Product Specification	Ph. Int.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in any RRA or NEML, Paediatric zinc sulfate oral solution monograph in international pharmacopoeia under the heading of Additional information specifies that "*Available strengths: 10 mg or 20 mg of zinc per 5 mL*"
	Me-too status	Zincbar Syrup by MBL 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[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Zinc (as Sulphate monohydrate)…20mg
	Decision: Approved with following label claim: **Each 5ml Contains:** **Zinc (as Sulphate monohydrate)…20mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
84.	**Name and address of manufacturer / Applicant**	**M/s Searle IV Solutions Pvt Ltd 1.5 km, Manga Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Levoxin Opthalmic Solution
	Composition	Each ml Contains: Levofloxacin Hemihydrate Eq. To Levofloxacin…15mg
	Diary No. Date of R& I & fee	Dy No. 14053: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Lequix Eye Drops by Schazoo
	GMP status	DML renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025
	Remarks of the Evaluator[3].	• Firm has eye drops (general) section as per renewal of DML letter dated 11-04-2016. • 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.	
85.	**Name and address of manufacturer / Applicant**	**M/s Searle IV Solutions Pvt Ltd 1.5 km, Manga Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Nevan Opthalmic Suspension
	Composition	Each ml Contains: Nepafenac…1mg
	Diary No. Date of R& I & fee	Dy No. 14047: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-inflammatory agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Acukat Ophthalmic Suspension by Genix Pharma
	GMP status	DML renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025
	Remarks of the Evaluator[3].	• Firm has eye drops (general) section as per renewal of DML letter dated 11-04-2016.
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
86.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Vimpil 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Dy No. 15213: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
87.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Vimpil 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Dy No. 15212: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
88.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Ranidin Injection 50mg
	Composition	Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine…50mg
	Diary No. Date of R& I & fee	Dy No. 15198: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	H2 – receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Zantac injection by GSK
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products.	
89.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Topsar 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R& I & fee	Dy No. 15201: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
90.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Topsar 40mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy No. 15202: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
91.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Topsar 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg
	Diary No. Date of R& I & fee	Dy No. 15203: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	

	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
92.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Velsar 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…80mg
	Diary No. Date of R& I & fee	Dy No. 15204: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Valtec Tablets by Tabros
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
93.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.**
	Brand Name +Dosage Form + Strength	Velsar 160mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 15205: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Valtec Tablets by Tabros
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator[3].	
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
94.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals Pvt Ltd 21-km Ferozpur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Sarpin Tablet 5/80mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Dy No. 14951: 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	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	GMP certificate issued to M/s Shrooq Pharma based upon evaluation conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
95.	**Name and address of manufacturer / Applicant**	**M/s Shrooq Pharmaceuticals Pvt Ltd 21-km Ferozpur Road, Lahore, Pakistan**

	Brand Name +Dosage Form + Strength	Sarpin Tablet 10/320mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…10mg Valsartan…320mg
	Diary No. Date of R& I & fee	Dy No. 14951: 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	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	GMP certificate issued to M/s Shrooq Pharma based upon evaluation conducted on 29-10-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
96.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Amoval 5/80mg Tablet
	Composition	Each Tablet Contains: Amlodipine as Besylate…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Dy No. 13438: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…80mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Amlodipine as Besylate…5mg** **Valsartan…80mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from film uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
97.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Amoval 5/160mg Tablet
	Composition	Each Tablet Contains: Amlodipine as Besylate…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 13439: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis

	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…160mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Amlodipine as Besylate…5mg** **Valsartan…160mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from film uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
98.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Amoval 10/160mg Tablet
	Composition	Each Tablet Contains: Amlodipine as Besylate…10mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 13440: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Amlodipine as Besylate…10mg Valsartan…160mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Amlodipine as Besylate…10mg** **Valsartan…160mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from film uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
99.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Hepcon Infusion
	Composition	Each Vial Contains: L-OR&Ithine L-Aspartate…5g/10ml
	Diary No. Date of R& I & fee	Dy No. 13436: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Amino Acid (Hepato Protective Lipotropic)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Hepa-Merz 5 g / 10 ml infusion solution concentrate (Austria Approved) as 10ml ampoule
	Me-too status	Hepanil Infusion Concentrate 5gm/10ml by Medicraft
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.

		• The RRA approved product is available in 10ml ampoule while you have applied the formulation in 10ml vial, clarification is required in this regard.
	Decision: Deferred for following submissions: • **Evidence of required manufacturing facility / section approval letter from Licensing Division.** • **Clarification, since the reference product is available in 10ml ampoule while you have applied the formulation in 10ml vial.** • **Evidence of requisite testing facility.** • **Latest GMP inspection report conducted within a period of last three years.**	
100.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Hepcon Syrup
	Composition	L-OR&Ithine L-Aspartate…300mg/ml Nicotinamide…24mg/5ml Riboflavin Sodium Phaspate…0.76mg/5ml
	Diary No. Date of R& I & fee	Dy No. 13435: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Amino Acid (Hepato Protective Lipotropic)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	OR&Ivit Syrup by English Pharma
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Submit complete label claim as per RRA approved product along with submission of full fee.
	Decision: Deferred for following submissions: • **Evidence of required manufacturing facility / section approval letter from Licensing Division.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of complete label claim as per the innovator's product along with submission of full fee of registration.** • **Evidence of requisite testing facility.** • **Latest GMP inspection report conducted within a period of last three years.**	
101.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Rabrin 400mg Capsule
	Composition	Each Capsule Contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	Dy No. 13444: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Xolox Capsule byFerozesons
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	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 following submissions:	

	• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Latest GMP inspection report conducted within a period of last three years.**	
102.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Rabrin 400mg Tablet
	Composition	Each Tablet Contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	Dy No. 13441: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Alcorib tablets by Searle
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	•
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
103.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Rabrin 500mg Tablet
	Composition	Each Tablet Contains: Ribavirin…500mg
	Diary No. Date of R& I & fee	Dy No. 13442: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Alcorib tablets by Searle
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	•
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
104.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Rabrin 600mg Tablet
	Composition	Each Tablet Contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	Dy No. 13443: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Alcorib tablets by Searle
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	•
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	

105.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Swicef 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Cefixime as trihydrate…200mg
	Diary No. Date of R& I & fee	Dy No. 16843: 07-03-2019 PKR 20,000/-: 07-03-2019
	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.	USFDA Approved
	Me-too status	Liskoxime Tablet by Lisko pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Registration Board decided to reject the application since the firm does not have requisite manufacturing facility / section approval from Licensing Division DRAP.	
106.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Celebox 100mg Capsule
	Composition	Each Capsule Contains: Celecoxib…100mg
	Diary No. Date of R& I & fee	Dy No. 16850: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Cewim Capsule by Wimits pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	• The applied product falls under WHO ATC class L01XX33 as well as M01AH01 and Registration Board in its 297th meeting decided to allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrextare etc. in the "Anti-cancer" section only (being high risk products).
	Decision: Approved.	
107.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Celebox 200mg Capsule
	Composition	Each Capsule Contains: Celecoxib…200mg
	Diary No. Date of R& I & fee	Dy No. 16851: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Cewim Capsule by Wimits pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	• The applied product falls under WHO ATC class L01XX33 as well as M01AH01 and Registration Board in its 297th meeting decided to

		allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrexate etc. in the "Anti-cancer" section only (being high risk products).
	Decision: Approved.	
108.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Dolium C 20/15 mg Tablet
	Composition	Each Tablet Contains: Cinnarizine…20mg Domperidone Maleate Eq. To Domperidone…15mg
	Diary No. Date of R& I & fee	Dy No. 16844: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anti-emetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Dozin Tablet by Hilton Pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	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 adopted by the Registration Board in its 275th meeting.	
109.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Fena 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…60mg
	Diary No. Date of R& I & fee	Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihistamines For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Fexet Tablets by Getz
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
110.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Fena 120mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…120mg
	Diary No. Date of R& I & fee	Dy No. 16853: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihistamines For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Fexet Tablets by Getz
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.

	Remarks of the Evaluator[3].	•
	Decision: Approved.	
111.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	K-Cit Tablet
	Composition	Each Extended Release Tablet Contains: Potassium Citrate…10mg
	Diary No. Date of R& I & fee	Dy No. 16845: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Mineral Supplements
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lithocit Tablet by Getz
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Extended Release Tablet Contains: Potassium Citrate…..10mEq (1080mg)
	Decision: Approved with following label claim: **Each Extended Release Tablet Contains:** **Potassium Citrate…..10mEq (1080mg)** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
112.	**Name and address of manufacturer / Applicant**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Xofyl 200mg Tablet
	Composition	Each Tablet Contains: Doxofylline…200mg
	Diary No. Date of R& I & fee	Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other Systemic Drugs For Obstructive Airway Diseases
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house 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	GMP certificate issued based upon inspection conducted on 28-02-2020
	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. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	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 adopted by the Registration Board in its 275th meeting.**	
113.	**Name and address of manufacturer / Applicant**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Xofyl Injection 100mg/10ml
	Composition	Each 10ml Ampoule Contains: Doxofylline…100mg
	Diary No. Date of R& I & fee	Dy No. 16052: 07-03-2019

		PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	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	GMP certificate issued based upon inspection conducted on 28-02-2020
	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. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	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 adopted by the Registration Board in its 275th meeting.**	
114.	**Name and address of manufacturer / Applicant**	**M/s Trillium Pharmaceuticals Pvt Ltd. Plot No. C-3 & C-4, Value Addition City, Faisalabad**
	Brand Name +Dosage Form + Strength	Tridic SR 50mg Capsule
	Composition	Each Capsule Contains SR Pellets: Diclofenac Sodium SR Pellets…50mg
	Diary No. Date of R& I & fee	Dy No. 16427: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ayanac 50mg SR Capsule
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • 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 following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).** • **Latest GMP inspection report conducted within a period of last three years.**	
115.	**Name and address of manufacturer / Applicant**	**M/s Trillium Pharmaceuticals Pvt Ltd. Plot No. C-3 & C-4, Value Addition City, Faisalabad**
	Brand Name +Dosage Form + Strength	Tridic SR 100mg Capsule
	Composition	Each Capsule Contains SR Pellets: Diclofenac Sodium SR Pellets…100mg
	Diary No. Date of R& I & fee	Dy No. 16428: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Arthonil Capsule by Batala Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Diclofenac sodium (as SR pellets)…100mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Diclofenac sodium (as SR pellets)…100mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
116.	**Name and address of manufacturer / Applicant**	**M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small Industries Estate, Sargodha**
	Brand Name +Dosage Form + Strength	Detrin 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron…8mg
	Diary No. Date of R& I & fee	Dy No. 13633: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Danset Tablet by CCL
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Ondansetron (as hydrochloride dihydrate)…8mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Ondansetron (as hydrochloride dihydrate)…8mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
117.	**Name and address of manufacturer / Applicant**	**M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small Industries Estate, Sargodha**
	Brand Name +Dosage Form + Strength	Triglip 50/500 mg Tablet
	Composition	Each Film Tablet Contains: Sitagliptin as Sitagliptin Phosphate Monohydrate…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 13643: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Treivamet Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
118.	**Name and address of manufacturer / Applicant**	**M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar**
	Brand Name +Dosage Form + Strength	Hepdisol 200mg Tablet
	Composition	Each Tablet Contains: Rifaximin…200mg
	Diary No. Date of R& I & fee	Dy No. 16437: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Axibol Tablet by Genetics Pharma
	GMP status	Date of Inspection 31-12-2021. Satisfactory level of GMP compliance.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin…200mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rifaximin…200mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
119.	**Name and address of manufacturer / Applicant**	**M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar**
	Brand Name +Dosage Form + Strength	Hepdisol 550mg Tablet
	Composition	Each Tablet Contains: Rifaximin…550mg
	Diary No. Date of R& I & fee	Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Axibol Tablet by Genetics Pharma
	GMP status	Date of Inspection 31-12-2021. Satisfactory level of GMP compliance.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin…550mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rifaximin…550mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
120.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	M Sulpade 100mg Tablet

	Composition	Each Tablet Contains: Amisulpride…100mg
	Diary No. Date of R& I & fee	Dy No. 14418: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Amis Tablets by Genome Pharmaceuticals
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
121.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	U Metab 50mg Tablet
	Composition	Each Tablet Contains: Clomifene Citrate…50mg
	Diary No. Date of R& I & fee	Dy No. 14424: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Vogi Tablet by Genix Pharma
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	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. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
122.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awaxetine 20mg Capsule
	Composition	Each Delayed Release Capsule Contains: Duloxetine As Hcl…20mg
	Diary No. Date of R& I & fee	Dy No. 14428: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…20mg

	Decision: Approved with following label claim: **Each Capsule Contains:** **Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…20mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
123.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awaxetine 30mg Capsule
	Composition	Each Delayed Release Capsule Contains: Duloxetine As Hcl…30mg
	Diary No. Date of R& I & fee	Dy No. 14429: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…30mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…30mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
124.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awaxetine 60mg Capsule
	Composition	Each Delayed Release Capsule Contains: Duloxetine As Hcl…60mg
	Diary No. Date of R& I & fee	Dy No. 14435: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).

		• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…60mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…60mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
125.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Floxet Capsule 20mg
	Composition	Each Capsule Contains: Fluoxetine HCl…20mg
	Diary No. Date of R& I & fee	Dy No. 14427: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Wintin capsule by Winlet Pharma
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Fluoxetine (as HCl)…20mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Fluoxetine (as HCl)…20mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
126.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awa Cet 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Dy No. 14409: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lumark Tablet by Searle
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	

	• **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
127.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awa Cet 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 14410: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lumark Tablet by Searle
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
128.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awa Cet 750mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…750mg
	Diary No. Date of R& I & fee	Dy No. 14411: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lumark Tablet by Searle
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
129.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awa Cet 1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…1000mg
	Diary No. Date of R& I & fee	Dy No. 14412: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lumark Tablet by Searle
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	

130.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	U Met 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin HCl …200mg
	Diary No. Date of R& I & fee	Dy No. 14422: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Biguanides
	Type of Form	Form 5
	Finished Product Specification	USP
	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	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • 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
	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 adopted by the Registration Board in its 275th meeting.** • **Latest GMP inspection report conducted within a period of last three years.**	
131.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	U Met 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin HCl …500mg
	Diary No. Date of R& I & fee	Dy No. 14423: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Biguanides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Glucophage Tablet by Martin Dow
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
132.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Co Folanz Tablet 3/25mg
	Composition	Each Capsule Contains: Olanzapine…3mg Fluoxetine As HCl…25mg
	Diary No. Date of R& I & fee	Dy No. 14419: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
133.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Co Folanz Tablet 6/25mg
	Composition	Each Capsule Contains: Olanzapine…6mg Fluoxetine As HCl…25mg
	Diary No. Date of R& I & fee	Dy No. 14420: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
134.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Co Folanz Tablet 12/25mg
	Composition	Each Capsule Contains: Olanzapine…12mg Fluoxetine As HCl…25mg
	Diary No. Date of R& I & fee	Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
135.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	U Saprox CR 12.5mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Paroxetine HCl…12.5mg
	Diary No. Date of R& I & fee	Dy No. 14415: 07-03-2019

		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Seroxat CR Tablet by GSK
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each enteric, film coated, controlled release tablet contains: Paroxetine (as HCl)…12.5mg
	Decision: Approved with following label claim: **Each enteric, film coated, controlled release tablet contains:** **Paroxetine (as HCl)…12.5mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
136.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	U Saprox CR 25mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Paroxetine HCl…25mg
	Diary No. Date of R& I & fee	Dy No. 14416: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Seroxat CR Tablet by GSK
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each enteric, film coated, controlled release tablet contains: Paroxetine (as HCl)….25mg
	Decision: Approved with following label claim: **Each enteric, film coated, controlled release tablet contains:** **Paroxetine (as HCl)….25mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
137.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	U Saprox CR 37.5mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Paroxetine Hcl…37.5mg
	Diary No. Date of R& I & fee	Dy No. 14417: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Seroxat CR Tablet by GSK
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each enteric, film coated, controlled release tablet contains: Paroxetine (as HCl)….37.5mg
	Decision: Approved with following label claim: **Each enteric, film coated, controlled release tablet contains:** **Paroxetine (as HCl)…37.5mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
138.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Stigamet 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 14413: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Treivamet Tablet by Getz
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin HCl…500mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Sitagliptin as Phosphate Monohydrate…50mg** **Metformin HCl…500mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
139.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Stigamet 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 14414: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Treivamet Tablet by Getz
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin HCl…1000mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Sitagliptin as Phosphate Monohydrate…50mg** **Metformin HCl…1000mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
140.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Antacid 254/237.5mg/5ml Oral Solution
	Composition	Each 5ml Contains: Aluminium Hydroxide …254mg Magnesium Carbonate…237.5mg
	Diary No. Date of R& I & fee	Dy No. 16074: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house 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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	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. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	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 adopted by the Registration Board in its 275th meeting.**	
141.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Cardil 12.5mg Tablet
	Composition	Each Tablet Contains: Carvedilol…12.5mg
	Diary No. Date of R& I & fee	Dy No. 16339: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Carveda tablet by Ferozesons
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
142.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Cardil 25mg Tablet
	Composition	Each Tablet Contains: Carvedilol…25mg
	Diary No. Date of R& I & fee	Dy No. 16344: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Carveda tablet by Ferozesons
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
143.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Ibabrine 5mg Tablet
	Composition	Each Tablet Contains: Ivabradine (as HCl)…5mg
	Diary No. Date of R& I & fee	Dy No. 16078: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ivadine Tablet by Pharmevo
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Ivabradine (as HCl)…5mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Ivabradine (as HCl)…5mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
144.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Ibabrine 7.5mg Tablet
	Composition	Each Tablet Contains: Ivabradine Hcl…7.5mg
	Diary No. Date of R& I & fee	Dy No. 16077: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Ivadine Tablet by Pharmevo
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Ivabradine (as HCl)…7.5mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Ivabradine (as HCl)…7.5mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
145.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Sparmid 500mg Tablet
	Composition	Each Tablet Contains: Nitazoxanide…500mg
	Diary No. Date of R& I & fee	Dy No. 16364: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diranide Tablet by MKB Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Nitazoxanide…500mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Nitazoxanide…500mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
146.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Ronrox 1mg Tablet
	Composition	Each Tablet Contains: Ropinirole (as HCl)…1mg
	Diary No. Date of R& I & fee	Dy No. 16064: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ropinirole Tablet by Mass Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Ropinirole (as HCl)…1mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Ropinirole (as HCl)…1mg**	

	• **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
147.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Ronrox 2mg Tablet
	Composition	Each Tablet Contains: Ropinirole (as HCl)…2mg
	Diary No. Date of R& I & fee	Dy No. 16065: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ropinirole Tablet by Mass Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Ropinirole (as HCl)…2mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Ropinirole (as HCl)…2mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
148.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Tarblend Topical Solution
	Composition	Each ml Contains: Polytar……..1%
	Diary No. Date of R& I & fee	Dy No. 16055: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	keratoplastics
	Type of Form	Form 5
	Finished Product Specification	USP
	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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	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. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	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 adopted by the Registration Board in its 275th meeting.**	
149.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Mimal Z 15mg/3ml Injection
	Composition	Each 3ml ampoule Contains: Midazolam (as HCl)…15mg
	Diary No. Date of R& I & fee	Dy No. 16085: 07-03-2019 PKR 20,000/-: 07-03-2019

	Pharmacological Group	Benzodiazepine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Midza Injection by ameer Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Firm has submitted letter of renewal of DML dated 10-08-2015 which specifies Liquid injection ampoule (psychotropic) section.
	Decision: Approved.	
150.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Glitamin 1/500mg Tbalet
	Composition	Each Tablet Contains: Rosiglitazone (as Maleate)…1mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 16083: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rosiform Tablet by CCL
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)…1mg Metformin HCl…500mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Rosiglitazone (as Maleate)…1mg** **Metformin HCl…500mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
151.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Glitamin 2/500mg Tablet
	Composition	Each Tablet Contains: Rosiglitazone (as Maleate)…2mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 16067: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rosiform Tablet by CCL
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)…2mg

		Metformin HCl…500mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Rosiglitazone (as Maleate)…2mg** **Metformin HCl…500mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
152.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Glitamin 4/500mg Tablet
	Composition	Each Tablet Contains: Rosiglitazone (as Maleate)…4mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 16070: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rosiform Tablet by CCL
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)…4mg Metformin HCl…500mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Rosiglitazone (as Maleate)…4mg** **Metformin HCl…500mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
153.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Glitamin plus 2mg/1000mg Tablet
	Composition	Each Tablet Contains: Rosiglitazone (as Maleate)…2mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rosiform Tablet by CCL
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)…2mg Metformin HCl…1000mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Rosiglitazone (as Maleate)…2mg** **Metformin HCl…1000mg**	

	• **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
154.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Glitamin plus 4mg/1000mg Tablet
	Composition	Each Tablet Contains: Rosiglitazone (as Maleate)…4mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 16095: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rosiform Tablet by CCL
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)…4mg Metformin HCl…1000mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Rosiglitazone (as Maleate)…4mg** **Metformin HCl…1000mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
155.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Holip 5mg/ml Injection
	Composition	Each 1ml ampoule Contains: Haloperidol (as Lactate)…5mg
	Diary No. Date of R& I & fee	Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Ceretek Injection by Schazoo Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
156.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Nitanide 100mg Dry Powder suspension
	Composition	Each 5ml Contains: Nitazoxanide…100gm
	Diary No. Date of R& I & fee	Dy No. 16081: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved

	Me-too status	Diranide Tablet by MKB Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications.	
157.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Venlox 75mg Tablet
	Composition	Each Tablet Contains: Venlafexine (as HCl)…75mg
	Diary No. Date of R& I & fee	Dy No. 16062: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Velax Tablet by Schazoo Zaka
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Venlafexine (as HCl)…75mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Venlafexine (as HCl)…75mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
158.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Fluzex 25mg/ml Injection
	Composition	Each ml Contains: Fluphenazine Deconate…25mg
	Diary No. Date of R& I & fee	Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Adecate 25mg/ml Injection by Adamjee Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
159.	**Name and address of manufacturer / Applicant**	**M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Zolret 2.5mg Tablet
	Composition	Each Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy No. 13949: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Aromatase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved

	Me-too status	Femara Tablet by Novartis
	GMP status	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.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Letrozole…2.5mg
	Decision: Registration Board approved registration of product with following label claim 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. **Each Film Coated Tablet Contains:** **Letrozole…2.5mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
160.	**Name and address of manufacturer / Applicant**	**M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Zorid 100mg Tablet
	Composition	Each Tablet Contains: Levosulpride…100mg
	Diary No. Date of R& I & fee	Dy No. 13956: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Medpride tablet by Medpharm Research Lab
	GMP status	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.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • 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 following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Latest GMP inspection report conducted within a period of last three years.**	
161.	**Name and address of manufacturer / Applicant**	**M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Gpenta 50mg Tablet
	Composition	Each SR Tablet Contains: Tapentadol…50mg
	Diary No. Date of R& I & fee	Dy No. 13951: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Analgesics, opioids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	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.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee • Stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Prolonged Release Tablet Contains: Tapentadol (as maleate hemihydrate)…50mg
	Decision: Deferred for following submissions: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee** • **Stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.** • **Latest GMP inspection report conducted within a period of last three years.** • **Revision of the formulation and label claim as per the innovator's product along with submission of full fee of registration.**	
162.	**Name and address of manufacturer / Applicant**	**M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Gpenta 100mg Tablet
	Composition	Each SR Tablet Contains: Tapentadol…100mg
	Diary No. Date of R& I & fee	Dy No. 13949: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Analgesics, opioids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	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.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee • Stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Prolonged Release Tablet Contains: Tapentadol (as maleate hemihydrate)…100mg
	Decision: Deferred for following submissions: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee** • **Stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.** • **Latest GMP inspection report conducted within a period of last three years.** • **Revision of the formulation and label claim as per the innovator's product along with submission of full fee of registration.**	

163.	**Name and address of manufacturer / Applicant**	**M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K**
	Brand Name +Dosage Form + Strength	Fenbro-67 mg Capsule
	Composition	Each Capsule Contains: Fenofibrate……67mg
	Diary No. Date of R& I & fee	Dy No. 16814: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lebirat capsule by Fynk Pharma
	GMP status	Last GMP inspection was conducted on 27-6-2018 concluded good GMP.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
164.	**Name and address of manufacturer / Applicant**	**M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K**
	Brand Name +Dosage Form + Strength	Solobron 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…5mg
	Diary No. Date of R& I & fee	Dy No. 16813: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Solif Tablet by Global
	GMP status	Last GMP inspection was conducted on 27-6-2018 concluded good GMP.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
165.	**Name and address of manufacturer / Applicant**	**M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K**
	Brand Name +Dosage Form + Strength	Solobron 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…10mg
	Diary No. Date of R& I & fee	Dy No. 16815: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Solif Tablet by Global
	GMP status	Last GMP inspection was conducted on 27-6-2018 concluded good GMP.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications.	

	• **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
166.	**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	Spacmic 80/80 mg Tablet
	Composition	Each Sugar Coated Tablet Contains: Hydrated Phloroglucinol…80mg Trimethyl Phloroglucinol…80mg
	Diary No. Date of R& I & fee	Dy No. 16934: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	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 by Wnsfield
	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[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
167.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Disten 5/80mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate…..5mg Valsartan…….80mg
	Diary No. Date of R& I & fee	Dy No. 16960: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Amlodipine Besylate Eq. To Amlodipine…5mg Valsartan…….80mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Amlodipine Besylate Eq. To Amlodipine…5mg** **Valsartan…….80mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
168.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	L zid 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…600mg

	Diary No. Date of R& I & fee	Dy No. 16961: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nezkil Tablet by S.J&G Fazul Ellahie
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
169.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Otenz 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine…5mg
	Diary No. Date of R& I & fee	Dy No. 16965: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olpine Tablet by Fynk Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	
	Decision: Approved.	
170.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Otenz 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine…10mg
	Diary No. Date of R& I & fee	Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olpine Tablet by Fynk Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	
	Decision: Approved.	
171.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Dlemet Plus 20/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan…20mg Amlodipine…5mg
	Diary No. Date of R& I & fee	Dy No. 16969: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Amlodipine Besylate Eq. To Amlodipine…5mg Olmesartan Medoxomil…20mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Amlodipine Besylate Eq. To Amlodipine…5mg** **Olmesartan Medoxomil…20mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
172.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Dlemet Plus 20/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan…20mg Amlodipine…10mg
	Diary No. Date of R& I & fee	Dy No. 16970: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Amlodipine Besylate Eq. To Amlodipine…10mg Olmesartan Medoxomil…20mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Amlodipine Besylate Eq. To Amlodipine…10mg** **Olmesartan Medoxomil…20mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
173.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Dlemet Plus 40/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan…40mg Amlodipine…5mg
	Diary No. Date of R& I & fee	Dy No. 16971: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Amlodipine Besylate Eq. To Amlodipine…5mg Olmesartan Medoxomil…40mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Amlodipine Besylate Eq. To Amlodipine…5mg** **Olmesartan Medoxomil…40mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
174.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Glitamet 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 16959: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Approved
	Me-too status	Galmet Tablet by Vision Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
175.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Varbet 16mg Tablet
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…16mg
	Diary No. Date of R& I & fee	Dy No. 16167: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
176.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Varbet 24mg Tablet
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…24mg

	Diary No. Date of R& I & fee	Dy No. 16168: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
177.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Varbet 48mg Tablet
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…48mg
	Diary No. Date of R& I & fee	Dy No. 16169: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
178.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Carvol 6.25mg Tablet
	Composition	Each Film Coated Tablet Contains: Carvedilol…6.25mg
	Diary No. Date of R& I & fee	Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Carveda tablet by Ferozesons
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol…6.25mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Carvedilol…6.25mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
179.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	FBX 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat…80mg
	Diary No. Date of R& I & fee	Dy No. 16175: 07-03-2019

		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-gout Preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zurig Tablet by Getz
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
180.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Olme 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg
	Diary No. Date of R& I & fee	Dy No. 16158: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olmie Tablet by Getz
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
181.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Olme 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg
	Diary No. Date of R& I & fee	Dy No. 16164: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olmie Tablet by Getz
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
182.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Olme Plus 40/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg Amlodipine Besylate Eq To Amlodipine…5mg
	Diary No. Date of R& I & fee	Dy No. 16159: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
183.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Olme Plus 20/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg Amlodipine Besylate Eq To Amlodipine…10mg
	Diary No. Date of R& I & fee	Dy No. 16157: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
184.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Olme Plus 40/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg Amlodipine Besylate Eq To Amlodipine…10mg
	Diary No. Date of R& I & fee	Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
185.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Helirab 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Rabeprazole Sodium…20mg
	Diary No. Date of R& I & fee	Dy No. 16658: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Protorib Tablet by Helix
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
186.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Riswrd 3mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone …3mg
	Diary No. Date of R& I & fee	Dy No. 16172: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Neo-Risp Tablet by Wilshire
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone …3mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Risperidone …3mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
187.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Riswrd 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone …4mg
	Diary No. Date of R& I & fee	Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Neo-Risp Tablet by Wilshire
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone …4mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Risperidone …4mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
188.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Muroz 500mcg Tablet

	Composition	Each Film Coated Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy No. 16668: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Vitamin B12 analogue
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification but available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Methycobal tablet by Hilton
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Sugar Coated Tablet Contains: Mecobalamin…500mcg
	Decision: Approved with JP specifications and with following label claim: **Each Sugar Coated Tablet Contains:** **Mecobalamin…500mcg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to sugar coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
189.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	A-Zint 6/25 mg Capsule
	Composition	Each Capsule Contains: Olanzapine…6mg Fluoxetine…25mg
	Diary No. Date of R& I & fee	Dy No. 16680: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Olanzapine (as HCl)…6mg Fluoxetine…25mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Olanzapine (as HCl)…6mg** **Fluoxetine…25mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
190.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	D-Tam Plus 20/5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate Eq. To Amlodipine…5mg Olmesartan Medoxomil…20mg
	Diary No. Date of R& I & fee	Dy No. 17372: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
191.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Pixel CR 12.5mg Tablet
	Composition	Each Film Coated Controlled Release Tablet Contains: Paroxetine As Hcl Hemihydrate…12.5mg
	Diary No. Date of R& I & fee	Dy No. 16679: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Seroxat CR Tablet by GSK
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each enteric, film coated, controlled release tablet contains: Paroxetine (as HCl)…12.5mg
	Decision: Approved with following label claim: **Each enteric, film coated, controlled release tablet contains:** **Paroxetine (as HCl)…12.5mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
192.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	C-Tol 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM France Approved
	Me-too status	Myolax tablet by Genetics
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Thiocolchicoside…4mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Tablet Contains:** **Thiocolchicoside…4mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
193.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**

	Brand Name +Dosage Form + Strength	Winterm Injection 80mg/ml
	Composition	Each ml Contains: Artemether…80mg
	Diary No. Date of R& I & fee	Dy No. 14827: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Ph. Int.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in any RRA However its monograph is available in Ph. Int and is also available in NEML
	Me-too status	Artisrch Injection by Medisearch
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section. • WHO essential medicine list 2022 specifies Artemether IV: 80 mg per mL in 1 mL ampoule (oily injection) under the section Antimalarial medicines > For curative treatment.
	Decision: Registration Board deliberated the matter regarding availability of applied formulation in refrence regulatoryu authorities and while considering the recommendation of applied formulation in WHO essential medicine list, decided to approved the applied product.	
194.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Wincip 125mg/5ml Granules
	Composition	Each 5ml Granules Suspension Contains: Ciprofloxacin HCl…125mg
	Diary No. Date of R& I & fee	Dy No. 14651: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Registration Board in 269th meeting approved the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension
	Me-too status	Novidat suspension by Sami
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml of reconstituted suspension contains: Ciprofloxacin.....125mg
	Decision: Defferred the case. The registration Board discussed and deliberated the case in detail regarding the diluent and decided to constitute an expert working group consisting of members from RB, DRAP, national and International health professionls in the relevant fields, stake holders and member nominated by WHO. This working group will look into the matter considering all the technical aspects and will forward its report to RB for its consideration and decision.	
195.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Citolin Injection IM/IV
	Composition	Each 4ml Ampoule Contains: Citicoline as Sodium…250mg
	Diary No. Date of R& I & fee	Dy No. 14649: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	4ml ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Somazine 1000 mg, solution for injection: Each 4 ml ampoule contains 1000 mg citicoline (as sodium salt). Spain Approved
	Me-too status	Injcho 250mg/ml Injection (4ml) of Ameer & Adnan Pharma

	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 4ml Ampoule Contains: Citicoline as Sodium…1000mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each 4ml Ampoule Contains:** **Citicoline as Sodium…1000mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
196.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Citolin Injection IM/IV
	Composition	Each 4ml Ampoule Contains: Citicoline As Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 14648: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	4ml ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	CITICOLINA KERN PHARMA 500 mg solution for injection EFG is presented in transparent glass ampoules. Each 4 ml ampoule contains 500 mg CITICOLINE (as sodium salt). Spain Approved
	Me-too status	Seeto-las Injection 500mg/4ml of Astellas Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section.
	Decision: Approved with Innovator's specifications.	
197.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Deslo 5mg Tablet
	Composition	Each Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Destina Tablet by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine…5mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Desloratadine…5mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
198.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Diclo In 75mg/3ml Injection
	Composition	Each 3ml ampoule Contains:

		Diclofenac Sodium…75mg
	Diary No. Date of R& I & fee	Dy No. 14652: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM France Approved
	Me-too status	Dicloran Injection by Sami
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section.
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
199.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Windic L Injection 2ml
	Composition	Each 2ml ampoule Contains: Diclofenac Sodium…75mg Lignocaine HCl…20mg
	Diary No. Date of R& I & fee	Dy No. 14803: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	NSAID with local Anaesthetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diclofenac-Mepha 75 ampoules IM 1 ampoule of 2 ml contains: 75 mg diclofenac sodium, 20 mg Lidocaine hydrochloride (Swiss medics approved).
	Me-too status	Lisodim IM Injection by Surge
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section.
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
200.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Drotawin Injection 40mg/2ml
	Composition	Each 2ml Contains: Drotaverine As HCl…40mg
	Diary No. Date of R& I & fee	Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	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) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved)
	Me-too status	Dytra Injection by Tabros
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section.

		• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 2ml ampoule Contains: Drotaverine HCl…40mg
	Decision: Registration Board deliberated the matter in detail and observed that the applied formulation is approved by three European Union countries i.e., Hungary, Romania & Bulgaria wherein Hungary & Romania are also PIC/S Member countries and the applied formulation is also already approved by DRAP, The Board therefore decided to approved the product with with Innovator's specifications and with following label claim: **Each 2ml ampoule Contains:** **Drotaverine HCl…40mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
201.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Zippo Capsule 20mg
	Composition	Each Enteric Coated Pellets Contains: Duloxetine As Hcl…20mg
	Diary No. Date of R& I & fee	Dy No. 14791: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…20mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…20mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
202.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Zippo Capsule 30mg
	Composition	Each Enteric Coated Pellets Contains: Duloxetine As Hcl…30mg
	Diary No. Date of R& I & fee	Dy No. 14792: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.

	Remarks of the Evaluator[3].	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…30mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…30mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
203.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Drowznel Syrup 5mg/5ml
	Composition	Each 5ml Contains: Ebastine…5mg
	Diary No. Date of R& I & fee	Dy No. 14793: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ebastel 1 mg/ml oral solution Spain Approved
	Me-too status	Kestine oral liquid by Highnoon
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
204.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Fluzip Tablet 120mg
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…120mg
	Diary No. Date of R& I & fee	Dy No. 14807: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antihistamines For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Fexet Tablets by Getz
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
205.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	G Win 320mg Tablet
	Composition	Each Film Coated Tablet Contains: Gemifloxacin Mesylate…320mg
	Diary No. Date of R& I & fee	Dy No. 14805: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in FDA / applicant withdraw its application for Marketing authorization in EMA
	Me-too status	Gemixa tablet by Bosch Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	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. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Gemifloxacin (as mesylate)…320mg
	Decision: Registration Board was apprised that the applied formulation is discontinued in USFDA and the marketing authorization application in EMA has been withdrawn due to negative risk benefit ratio. Based upon the findings of the EMA, the Board decided as under: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Directed PE&R Division to present the detailed case in forthcoming meeting of Registration Board along with details of already registered products of same formulation.**	
206.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Valturn D 80mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Hydrochlorothiazide…80mg Valsartan…12.5mg
	Diary No. Date of R& I & fee	Dy No. 14779: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Thiazides, combinations with other drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nuval-D Tablet by Pharmevo
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
207.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Valturn D Tablet 160/25mg
	Composition	Each Film Coated Tablet Contains: Hydrochlorothiazide…160mg Valsartan…25mg
	Diary No. Date of R& I & fee	Dy No. 14780: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Thiazides, combinations with other drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nuval-D Tablet by Pharmevo
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
208.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Monofer 500mg/5ml Injection

	Composition	Each 5ml Contains: One Milimeter for Solution Contains 100mg Iron Isomaltoside 1000:500mg/5ml
	Diary No. Date of R& I & fee	Dy No. 14656: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5ml ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA approved
	Me-too status	Maltoside 500mg/5ml Injection of Nabiqasim
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml ampoule contains: Iron isomaltoside 1000 (ferric derisomaltose) eq to elemental iron …500mg
	Decision: Approved with following label claim: **Each 5ml ampoule contains:** **Iron isomaltoside 1000 (ferric derisomaltose) eq to elemental iron …500mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
209.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	W Malt 100mg Tablet
	Composition	Each Tablet Contains: Iron (iii) Hydroxide Polymaltose Equivalent To Elemental Iron…100mg
	Diary No. Date of R& I & fee	Dy No. 14806: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Hematinic
	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 approved
	Me-too status	Tyzofer Tablet by Jinnah Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each film coated tablet contains: Iron (III) Hydroxide Polymaltose Complex eq to Elemental Iron…100mg
	Approved with Innovator's specifications and with following label claim: **Each film coated tablet contains:** **Iron (III) Hydroxide Polymaltose Complex eq to Elemental Iron…100mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
210.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lakasawin Infusion 200mg/20ml
	Composition	Each ml Contains: Lacosamide……..10mg
	Diary No. Date of R& I & fee	Dy No. 14646: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5

	Finished Product Specification	BP
	Pack size & Demanded Price	20ml glass vial: As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lacolep Injection by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section.
	Decision: Approved.	
211.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Wincetam Injection 500mg/5ml
	Composition	Each 5ml ampoule contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 14786: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 100 mg / mL Concentrate for solution for infusion (MHRA Approved)
	Me-too status	Lumark Injection by Searle
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section.
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
212.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Levoride 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Dy No. 14797: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy approved.
	Me-too status	Levide tablet by Swiss Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Levosulpiride…25mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Tablet Contains:** **Levosulpiride…25mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
213.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Levoride Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Levosulpiride …50mg
	Diary No. Date of R& I & fee	Dy No. 14798: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Antipsychotic

	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy approved.
	Me-too status	Levide tablet by Swiss Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Levosulpiride…50mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Tablet Contains:** **Levosulpiride…50mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
214.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lidowin Injection 20mg/2ml
	Composition	Each 2ml ampoule contains: Lignocaine HCl…20mg
	Diary No. Date of R& I & fee	Dy No. 14644: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Local anesthetics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lycas Injection by Pharmedic Laboratories
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section.
	Decision: Approved.	
215.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Linxo Tablet 600mg
	Composition	Each Film Coated Tablet Contains: Linezolid…600mg
	Diary No. Date of R& I & fee	Dy No. 14790: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nezkil Tablet by S.J&G Fazul Ellahie
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
216.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Meconium 500mcg
	Composition	Each Sugar Coated Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy No. 14640: 07-03-2019 PKR 20,000/-: 04-03-2019

	Pharmacological Group	Vitamin B12 analogue
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification but available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Methycobal tablet by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	•
	Decision: Approved with JP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
217.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Nimso 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Nimsulide…100mg
	Diary No. Date of R& I & fee	Dy No. 14796: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	HPRA Ireland Approved
	Me-too status	Nise Tablet by Pharmevo
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
218.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Cetram 200mg/ml Oral Solution
	Composition	Each 5ml Contains: Piracetam…200mg
	Diary No. Date of R& I & fee	Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved.
	Me-too status	Nootropil Syrup by AGP
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam…1gm
	Decision: Approved with Innovator's specifications and with following label claim: **Each 5ml Contains:** **Piracetam…1gm** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
219.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Rabi Win 20mg Tablet
	Composition	Each Tablet Contains: Rabeprazole Sodium…20mg

	Diary No. Date of R& I & fee	Dy No. 14809: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Protorib Tablet by Helix
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Enteric Coated Tablet Contains: Rabeprazole Sodium…20mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Enteric Coated Tablet Contains:** **Rabeprazole Sodium…20mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
220.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Tindo 2mg Tablet
	Composition	Each Tablet Contains: Tizanidine (as HCl)…..…2mg
	Diary No. Date of R& I & fee	Dy No. 14801: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Movax Tablet by Sami
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
221.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Tranza Injection 500mg
	Composition	Each ml Contains: Tranexamic Acid…500mg
	Diary No. Date of R& I & fee	Dy No. 14643: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tranxet Injection by Bio-Labs
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml ampoule Contains: Tranexamic Acid…500mg
	Decision: Approved with following label claim: **Each 5ml ampoule Contains:**	

	Tranexamic Acid…500mg • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
222.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Tranza Injection 250mg
	Composition	Each ml Contains: Tranexamic Acid…250mg
	Diary No. Date of R& I & fee	Dy No. 14642: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification	JP
	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 last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (general) section. • 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
	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 adopted by the Registration Board in its 275th meeting.**	
223.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Wapival 250mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Valproate Semisodium…250mg
	Diary No. Date of R& I & fee	Dy No. 14804: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Epival Tablet by Abbott
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Enteric Coated Tablet Contains: Valproate Semisodium eq to valproic acid…250mg
	Decision: Approved with following label claim: **Each Enteric Coated Tablet Contains:** **Valproate Semisodium eq to valproic acid…250mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
224.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Wapival 500mg Tablet
	Composition	Each Enteric Coated Tablet Contains:

		Valproate Semisodium…500mg
	Diary No. Date of R& I & fee	Dy No. 14805: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Epival Tablet by Abbott
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Enteric Coated Tablet Contains: Valproate Semisodium eq to valproic acid…500mg
	Decision: Approved with following label claim: **Each Enteric Coated Tablet Contains:** **Valproate Semisodium eq to valproic acid…500mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
225.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Coartem DS Tablet
	Composition	Each Tablet Contains: Artemether …40mg Lumefantrine…240mg
	Diary No. Date of R& I & fee	Dy No. 13335: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Ph. Int.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO PQ formulation
	Me-too status	Artem DS Plus Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
226.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Riclofen 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Baclofen…10mg
	Diary No. Date of R& I & fee	Dy No. 13345: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Baclofa Tablet by Helix
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:

		Each Tablet Contains: Baclofen…10mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Baclofen…10mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
227.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	D Lorin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 13319: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Destina Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
228.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Ezestatin-2 Tablet
	Composition	Each Film Coated Tablet Contains: Ezetimibe…10mg Simvastatin…20mg
	Diary No. Date of R& I & fee	Dy No. 13361: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Simvax Plus Tablet by Evolution pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Ezetimibe…10mg Simvastatin…20mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Tablet Contains:** **Ezetimibe…10mg** **Simvastatin…20mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
229.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Wystaglobin Chewable Tablet
	Composition	Each Chewable Tablet Contains: Iron III Hydroxide Polymaltose Complex Eq. To Elemental Iron…100mg

		Folic Acid…0.35mg
	Diary No. Date of R& I & fee	Dy No. 13347: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Hematinic
	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	Fersip Fol Chewable Tablet by Scotmann Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
230.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Arrefloxacin 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levofloxacin As Hemihydrate…500mg
	Diary No. Date of R& I & fee	Dy No. 13367: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Leflox Tablet by Getz Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
231.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Lorin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Loratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 13320: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	USP
	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	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • 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
	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 adopted by the Registration Board in its 275th meeting.** • **Latest GMP inspection report conducted within a period of last three years.**	
232.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Pantazol 40mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Pantoprazole Sodium Eq. To Pantoprazole…40mg
	Diary No. Date of R& I & fee	Dy No. 13372: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Protium Tablet by Abbott
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Enteric Coated Tablet Contains: Pantoprazole (as sodium sesquihydrate)……40mg
	Decision: Approved with following label claim: **Each Enteric Coated Tablet Contains:** **Pantoprazole (as sodium sesquihydrate)……40mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
233.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Arrexan 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Rifaximin…200mg
	Diary No. Date of R& I & fee	Dy No. 13335: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Axibol Tablet by Genetics Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
234.	**Name and address of manufacturer / Applicant**	**M/s Skims Pharmaceuticals, 10/B Value Addition city, Khurrianwala, Faisalabad**
	Brand Name +Dosage Form + Strength	Skicon Capsule 150mg
	Composition	Each Capsule Contains: Fluconazole…150mg

	Diary No. Date of R& I & fee	Dy No. 16426: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antimycotics for systemic use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Candizole Capsule by Genetics Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
235.	**Name and address of manufacturer / Applicant**	**M/s Skims Pharmaceuticals, 10/B Value Addition city, Khurrianwala, Faisalabad**
	Brand Name +Dosage Form + Strength	Skical Sachet
	Composition	Each Sachet Contains: Calcium Carbonate…685mg Calcium Gluconate…20mg Calcium Lactate…200mg Asorbic Acid…500mg
	Diary No. Date of R& I & fee	Dy No. 16425: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Calcium + Vitamin
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Genzit Sachet 685/20/200/500mg by Rogen Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • 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 following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Latest GMP inspection report conducted within a period of last three years.**	
236.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Kacinon Injection 100mg/2ml
	Composition	Each 2ml Contains: Amikacin as Sulphate…1000mg
	Diary No. Date of R& I & fee	Dy No. 15123: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.

		• 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
	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 adopted by the Registration Board in its 275th meeting.** • **Evidence of required manufacturing facility / section approval letter from Licensing Division.**	
237.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Kacinon Injection 250mg/2ml
	Composition	Each 2ml Contains: Amikacin as Sulphate…250mg
	Diary No. Date of R& I & fee	Dy No. 15124: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • 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
	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 adopted by the Registration Board in its 275th meeting.** • **Evidence of required manufacturing facility / section approval letter from Licensing Division.**	
238.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lexim 125mg/ml Dry Powder suspension
	Composition	Each 5ml of reconstituted suspension contains: Cephalexin monohydrate…125mg
	Diary No. Date of R& I & fee	Dy No. 15147: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	Keflex suspension by AGP
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Firm has dry powder suspension (cephalosporin) section as per the GMP certificate issued on the basis of inspection dated 10-01-2022.

		• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml of reconstituted suspension contains: Cephalexin (as monohydrate)…125mg
	Decision: Approved with following label claim: **Each 5ml of reconstituted suspension contains:** **Cephalexin (as monohydrate)…125mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
239.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lexim 250mg/ml Dry Powder suspension
	Composition	Each 5ml of reconstituted suspension Contains: Cephalexin Monohydrate…250mg
	Diary No. Date of R& I & fee	Dy No. 15137: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	Keflex suspension by AGP
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Firm has dry powder suspension (cephalosporin) section as per the GMP certificate issued on the basis of inspection dated 10-01-2022. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml of reconstituted suspension contains: Cephalexin (as monohydrate)…250mg
	Decision: Approved with following label claim: **Each 5ml of reconstituted suspension contains:** **Cephalexin (as monohydrate)…250mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
240.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Emycin 125mg Granules
	Composition	Each 5ml of reconstituted suspension contains: Erythromycin…125mg
	Diary No. Date of R& I & fee	Dy No. 15138: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Xyrox-E 125mg Dry Suspension by Jawa Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Firm has dry powder suspension (General) section as per the GMP certificate issued on the basis of inspection dated 10-01-2022. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml of reconstituted suspension contains: Erythromycin (as ethyl succinate)…125mg
	Decision: Approved with following label claim: **Each 5ml of reconstituted suspension contains:**	

	Erythromycin (as ethyl succinate)…125mg • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
241.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Emycin 200mg Granules
	Composition	Each 5ml Contains: Erythromycin…200mg
	Diary No. Date of R& I & fee	Dy No. 15129: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Eryped granules for oral suspension of Abror Pharms (USFDA approved)
	Me-too status	Eryget 200mg/5ml (Granules) Suspension by Getz
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Firm has dry powder suspension (General) section as per the GMP certificate issued on the basis of inspection dated 10-01-2022. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml of reconstituted suspension contains: Erythromycin (as ethyl succinate)…200mg
	Decision: Approved with following label claim: **Each 5ml of reconstituted suspension contains:** **Erythromycin (as ethyl succinate)…200mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
242.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Biofen Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Flurbiprofen…50mg
	Diary No. Date of R& I & fee	Dy No. 15134: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dynasaid 50mg Tablets by Dynatis
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Sugar Coated Tablet Contains: Flurbiprofen…50mg
	Decision: Approved with following label claim: **Each Sugar Coated Tablet Contains:** **Flurbiprofen…50mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to sugar coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
243.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Elvox Tablet 250mg
	Composition	Each Film Coated Tablet Contains: Levofloxacin Hemihydrate eq to Levofloxacin Base…250mg

	Diary No. Date of R& I & fee	Dy No. 15135: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Leflox Tablet by Getz Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
244.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Elvox Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Levofloxacin Hemihydrate eq to Levofloxacin Base…500mg
	Diary No. Date of R& I & fee	Dy No. 15146: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Leflox Tablet by Getz Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
245.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Elvox Tablet 750mg
	Composition	Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base…750mg
	Diary No. Date of R& I & fee	Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Leflox Tablet by Getz Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
246.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Unicocin Injection 300mg/ml
	Composition	Each ml Contains: Lincomycin HCl Monohydrate…300mg
	Diary No. Date of R& I & fee	Dy No. 15143: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved (as 2ml vial) PMDA Japan Approved (as 1ml)
	Me-too status	Linkotrex Injection by Wimits Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Specify the exact fill volume of the applied product. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each ml Contains: Lincomycin (as HCl Monohydrate)…300mg
	Decision: Deferred for following submissions: • **Evidence of required manufacturing facility / section approval letter from Licensing Division.** • **Clarification regarding the exact fill volume of the applied product.** • **Revision of the formulation and label claim as per the innovator's product along with submission of full fee of registration.**	
247.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Entazolate Tablet 200/250mg
	Composition	Each Film Coated Tablet Contains: Metronidazole…200mg Diloxanide Furoate…250mg
	Diary No. Date of R& I & fee	Dy No. 15141: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Nitroimidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Mntazole Tablet by Jawa
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	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 adopted by the Registration Board in its 275th meeting.	
248.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Entazole DS Tablet 400/500mg
	Composition	Each Film Coated Tablet Contains: Metronidazole…400mg Diloxanide Furoate…500mg
	Diary No. Date of R& I & fee	Dy No. 15136: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Nitroimidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Mntazole Tablet by Jawa
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	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 adopted by the Registration Board in its 275th meeting.	

249.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Cyclin M Capsule 50mg
	Composition	Each Capsule Contains: Minocycline HCl…50mg
	Diary No. Date of R& I & fee	Dy No. 15126: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	My-Cin Capsule by Ciba Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Firm has capsule (General) section. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Minocycline (as HCl)…50mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Capsule Contains:** **Minocycline (as HCl)…50mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
250.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Anakort 40mg Injection
	Composition	Each ml Contains: Triamcinolone Acetonide…40mg
	Diary No. Date of R& I & fee	Dy No. 15133: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Glucocorticoid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Novacort injection by Novex Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Specify the fill volume of the applied product.
	Decision: Deferred for following submissions: • **Evidence of required manufacturing facility / section approval letter from Licensing Division.** • **Clarification regarding the exact fill volume of the applied product.**	
251.	**Name and address of manufacturer / Applicant**	**M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Miszin 10mg/5ml
	Composition	Each 5ml Contains: Zinc Sulphate…10mg
	Diary No. Date of R& I & fee	Dy No. 15139: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other Mineral Supplements
	Type of Form	Form 5
	Finished Product Specification	Ph. Int.
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in any RRA or NEML, Paediatric zinc sulfate oral solution monograph in international pharmacopoeia under the heading of Additional information specifies that "*Available strengths: 10 mg or 20 mg of zinc per 5 mL*"
	Me-too status	Zincbar Syrup by MBL Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Zinc (as Sulphate monohydrate)…10mg
	Decision: Approved with following label claim: **Each 5ml Contains:** **Zinc (as Sulphate monohydrate)…10mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

252.	**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 Gel 0.025%
	Composition	Each Gm of Gel Contains: Fluocinolone Actonide 0.25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13561 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	043445; "DERMOLONE GEL 0.025%" "VEGA."
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of 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.	
253.	**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	Bifyllin 600mg Film Coated Tablet
	Composition	Each Film Coated Tablet Contains: Bamifylline (As Hydrochloride) 600mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13539 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Methylxanthine
	Type of Form	Form-5
	Finished product Specifications	Maxitech Pharma
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	014936; "BAMIFIX 600mg Tablet" "Cheisi Pharma."
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of 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.	

254.	**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	Andar-H 16mg + 12.5mg Tablet
	Composition	Each Tablet Contains: Candesartan Cilexetil…….16mg Hydrochlorothiazide……..12.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13529 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND HCT® USFDA Approved.
	Me-too status (with strength and dosage form)	034675; "CANSAAR PLUS 16mg+12.5mg Tablet" "Abbott Pharm."
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Candesartan Cilexetil…….16mg** **Hydrochlorothiazide……..12.5mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
255.	**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 Ointment 0.025%
	Composition	Each Gm of Ointment Contains: Fluocinolone Acetonide…….. 0.25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13560 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SYNALAR® USFDA Approved.
	Me-too status (with strength and dosage form)	041892; "DERMOLONE OINTMENT 0.025%" "VEGA."
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	Decision: Approved.	
256.	**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	D-Light 50000 soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Vitamin D3…….50000IU
	Diary No. Date of R& I & fee	Form-5 Dy.No 13570 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specifications	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Altavita D3 50000 iu soft capsules HPRA
	Me-too status (with strength and dosage form)	097598; "HUESO-D 50000IU SOFT GELATIN CAPSULE" "VALOR/AL-HAMEED"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
257.	**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	Bitrex 4% Cream
	Composition	Each 100Gm Cream Contains: Benzoyl Peroxide….. 4g
	Diary No. Date of R& I & fee	Form-5 Dy.No 13565 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	organic compounds
	Type of Form	Form-5
	Finished product Specifications	Maxitech Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	019464; "BREVOXYL 4% Cream" "GSK"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of 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.	
258.	**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 Topical Solution 0.01%
	Composition	Each ml Contains: Fluocinolone Acetonide……. 0.1mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	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 adopted by the Registration Board in its 275th meeting.**	
259.	**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 25mg Soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains:

		Cyclosporin…… 25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13568 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sandimmune® Soft Gelatin Capsule USFDA Approved.
	Me-too status (with strength and dosage form)	Sandimum soft Gelatin Capsules NOVARTIS
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
260.	**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	TH-SALIC Topical Solution
	Composition	Each ml Contains: Coal Tar……..30mg Hydrocortisone…..10mg Salicylic Acid…….30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13545 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	Maxitech Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	"COSALIC LOTION" "CRYSTOLITE"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of 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.	
261.	**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	Vartan S 24/26mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan 24mg Sacubotril 26mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13535 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	As Per innovator Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Entresto® USFDA Approved.
	Me-too status (with strength and dosage form)	; "WILTRILL 24/20mg Tablet" "Helix Pharma"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	

	Decision: Deferred for submission of stability study data of three batches of drug product as per the guidelines provided in 293rd meeting of Registration Board.	
262.	**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	Fertrex N Cream 0.025%/0.5%
	Composition	Each Gm Cream Contains: Fluocinolone Acetonide 0.25mg Neomycin Sulphate 5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13558 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	029329; "BREVOXYL 4% Cream" "GSK"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of 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.	
263.	**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	Cilone Cream 0.01%/4%/0.05%
	Composition	Each Gm Cream Contains: Fluocinolone Acetonide 0.1mg Hydroquinone 40mg Tretinoin 0.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13555 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Corticosteroid / Hydroxy quinolone / Antifungal
	Type of Form	Form-5
	Finished product Specifications	Maxitech Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRI-LUMA Cream® USFDA Approved.
	Me-too status (with strength and dosage form)	071490; "TRIDERM Cream" "Shrooq Pharma"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
264.	**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	O Rice sachet
	Composition	Each Sachet Contains: Pre Cooked Rice Powder 6Gm Sodium Chloride 0.350Gm Potassium Chloride 0.580Gm Sodium Citrate 0.300Gm
	Diary No. Date of R& I & fee	Form-5 Dy.No 13576 dated 07-03-2019 Rs.20,000/- dated 06-03-2019

	Pharmacological Group	Electrolyte Replenisher
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	Hilyte-R powder sachet Hilton Pharma
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	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.** • **Confirmation of required manufacturing facility / section from Licensing Division.**	
265.	**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	Azetive Cream
	Composition	Each Gm Cream Contains: Azelaic Acid….. 0.2gm
	Diary No. Date of R& I & fee	Form-5 Dy.No 13554 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-microbial
	Type of Form	Form-5
	Finished product Specifications	Maxitech Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AZELEX Cream® USFDA Approved.
	Me-too status (with strength and dosage form)	012722; "SKINOREN Cream" "Bayer"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 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 CTD cases

a. Deferred cases of local manufacturing

266.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 30-12-2020 for following 4 sections.

		• Tablet (General) • Capsule (General) • Sachet (General) • Oinment / Cream / Gel (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. 7362: 16-03-2022
	Details of fee submitted	PKR 30,000/-: 14-01-2022
	The proposed proprietary name / brand name	**DEXZEN 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	
	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.			
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-01	T-02	T-01
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
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)	
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 23-02-2021 specifying purchase of 2Kg dexlansoprazole pellets 22.5%.
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]:

- GMP certificate / inspection report of the firm conducted within a period of last three years.

- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- 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 complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any method and procedures for preparation of each type of solution. Furthermore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- 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, since you have submitted COA of multiple irrelevant batches in this section.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.
- Section 3.2.S.6 specifies that the API manufacturer is using food grade double polyethylene bag for storing these pellets which are highly sensitive to moisture and light. Justification is required in this regard.
- Provide information in section 3.2.S.7.1 amd 3.2.S.7.2 as per CTD guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.
- The stability study of dexlansoprazole pellets performed by Vision Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.
- Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of dexlansoprazole pellets wherein the representative from the pellets manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarification is required in this regard.
- Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.
- Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be perfomed, since you have mentioned that pharmaceutical equivaelence is not required and then you have also provided a brief report of dexlansoprazole tablet in which all tests are not performed.
- Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter.
- Submit information in section 3.2.P.3 as per the guidance document which specifies that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified".
- Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1.
- Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "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. Proposals for the reprocessing of materials (if any) shall be justified. Any data to support this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified".

- Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "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."
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established.
- Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.
- Provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarification is required in this regard.
- Provide validation studies of the analytical method of drug product in section 3.2.P.5.3.
- Provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.
- Provide COA of the reference standard / working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard.
- Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."
- You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard.
- Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.
- Justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets.
- Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.
- Justify the dissolution test in which the acceptance criteria is NLT 75% in 5 hours which is against the specificatiosn of innovator's product.
- Justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter <711> as well as defined by Registration Board in its 293rd meeting.
- Provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule.
- Provide stability study data in a proper sequence by providing stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and sperators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - 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.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

Decision of 323rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response by the firm:

Sr. No	Short coming	Annexure

01	GMP certificate /inspection report of the firm conducted within a period of last three years.	Firm has not submitted GMP certificate / inspection report.
02	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.	Firm has **not** submitted QOS as per WHO template.
03	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 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
04	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.	Firm has **not** submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
05	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, since you have submitted COA of multiple irrelevant batches in this section.	Firm has submitted COA of batch number DLP664.
06	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of hese pellets or any other source of reference standard manufacturing.	Firm has **not** sumitted COA of reference / working standard.
07	Section 3.2.S.6 specifies that the API food grade double manufacturer is using polyethylene bag for storing these which are pellets highly sensitive to moisture and light. Justification is required in this regard.	Three polyethylene bag used for packing of pellets. Two transparent and one black color bags along with silica gel.
08	Provide information in section 3.2.S.7.1 and 3.2.S.7.2 as CTD per guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.	Firm has submitted information in section 3.2.S.7.1 and 3.2.S.7.2 as CTD per guidance document.
09	The stability study of Vision Dexlansoprazole pellets performed by Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.	Study performed at lab scale and in chamber they placed sample in pet bottle and for commercial they provide polythene bags and drum which is not possible in pet bottle.
10	Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of Dexlansoprazole pellets wherein the manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarifications required in this regard.	DMF provided by vision pharma
11	Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.	Submitted by the firm.

12	Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be performed, since you have mentioned that pharmaceutical equivalence is not required and then you have also provided a brief report of Dexlansoprazole tablet in which all tests are not performed.	Firm has submitted pharmaceutical equivalence studies against the comparator product manufactured by Weatherfolds pharma.
13	Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter	Firm has submitted results of comparative dissolution profile against the brand leader.
14	submit information in section 3.2.P.3 as per the guidance document which specifies that The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified"	Firm has submitted information in section 3.2.P.3 as per the guidance document.
15	Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1	Firm has submitted information in section 3.2.P.3.2 as per the guidance document.
16	Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "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. Proposals for the reprocessing of materials (if any) shall be justified. Any data t supports this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified"	Firm has submitted information in section 3.2.P.3.3 as per the guidance document.
17	Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "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."	Firm has submitted information in section 3.2.P.3.4 as per the guidance document.
18	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has **not** submitted process validation protocols.
19	Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.	Firm has submitted specifications of the drug product in section 3.2.P.5.1.
20	provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarifications required in this regard	Firm has submitted specifications of the drug product in section 3.2.P.5.2.

21	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Firm has **not** submitted complete validation studies of the analytical method of drug product in section 3.2. P.5.3.
22	provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of Dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.	Firm has submitted Batch analysis report of 3 stability batches.
23	Provide COA of the reference standard I working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard	Firm has **not** submitted COA of reference standard / working standard.
24	Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."	Firm has submitted details of container closure system.
25	You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard	Written mistakenly, revised and correct submitted.
26	Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.	Firm has submitted information in section 3.2.P.8.1 and 3.2.P.8.2.
27	justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets	Firm has now submitted dissolution test results at different medium in stability studies.
28	Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.	Firm has submitted specifications and analytical method of drug product.
29	justify the dissolution test in which the acceptance criteria NLT 75% in 5 hours which is against the specifications of innovator's product	Typo mistake Revised COA attached
30	justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter as well as defined by Registration Board in its 293d meeting	Corrected and resubmitted by the firm
31	provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule	Revised COA are submitted by the firm.
32	provide stability study data in a proper se stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and separators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out	Firm has submitted stability data in a proper sequence.
33	submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: • Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted response against the 6 points checklist as per CTD guidance document.

	• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin • Documents for the procurement of APl with approval from DRAP (in case of import). • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of both stability chambers	

Decision of 324th meeting: Deferred for following observations:

- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of hese pellets or any other source of reference standard manufacturing.
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established
- Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.
- Provide COA of the reference standard I working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard

Firm's response:

Sr.#	Observation	Reply
1.	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document	Submitted
2.	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.	Firm has submitted revised analytical method verification studies performed by M/s Wezen Pharmaceuticals.
3.	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.
4.	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has submitted revised process validation protocol including the critical steps, sampling plan, and evaluation criteria for the process of capsule filling, sealing and blistering.
5.	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Submitted.

6.	Provide COA of the reference standard in working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.

Decision: Deferred for submission of Pharmaceutical equivalence and Comparative Dissolution Profile (CDP) studies against the innovator's product.

267.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	has submitted copy of letter of grant of additional section dated 30-12-2020 for following 4 sections. • Tablet (General) • Capsule (General) • Sachet (General) • Oinment / Cream / Gel (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. 7363: 16-03-2022
	Details of fee submitted	PKR 30,000/-: 14-01-2022
	The proposed proprietary name / brand name	**DEXZEN 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	
	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.			
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-04	T-05	T-06
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
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)	

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 23-02-2021 specifying purchase of 2Kg dexlansoprazole pellets 22.5%.
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]:

- GMP certificate / inspection report of the firm conducted within a period of last three years.
- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- 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 complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any method and procedures for preparation of each type of solution. Furthermore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- 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, since you have submitted COA of multiple irrelevant batches in this section.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.
- Section 3.2.S.6 specifies that the API manufacturer is using food grade double polyethylene bag for storing these pellets which are highly sensitive to moisture and light. Justification is required in this regard.
- Provide information in section 3.2.S.7.1 amd 3.2.S.7.2 as per CTD guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.
- The stability study of dexlansoprazole pellets performed by Vision Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.
- Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of dexlansoprazole pellets wherein the representative from the pellets manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarification is required in this regard.
- Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.
- Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be perfomed, since you have mentioned that pharmaceutical equivaelence is not required and then you have also provided a brief report of dexlansoprazole tablet in which all tests are not performed.

- Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter.
- Submit information in section 3.2.P.3 as per the guidance document which specifies that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified".
- Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1.
- Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "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. Proposals for the reprocessing of materials (if any) shall be justified. Any data to support this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified".
- Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "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."
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established.
- Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.
- Provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarification is required in this regard.
- Provide validation studies of the analytical method of drug product in section 3.2.P.5.3.
- Provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.
- Provide COA of the reference standard / working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard.
- Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."
- You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard.
- Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.
- Justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets.
- Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.
- Justify the dissolution test in which the acceptance criteria is NLT 75% in 5 hours which is against the specificatiosn of innovator's product.
- Justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter <711> as well as defined by Registration Board in its 293rd meeting.
- Provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule.
- Provide stability study data in a proper sequence by providing stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample

for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and sperators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out.

- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - 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.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

Decision of 323rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response by the firm:

Sr. No	Short coming	Annexure
01	GMP certificate /inspection report of the firm conducted within a period of last three years.	Firm has not submitted GMP certificate / inspection report.
02	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.	Firm has **not** submitted QOS as per WHO template.
03	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 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
04	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.	Firm has **not** submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
05	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, since you have submitted COA of multiple irrelevant batches in this section.	Firm has submitted COA of batch number DLP664.
06	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of hese pellets or any other source of reference standard manufacturing.	Firm has **not** sumitted COA of reference / working standard.
07	Section 3.2.S.6 specifies that the API food grade double manufacturer is using polyethylene bag for storing these which are pellets highly sensitive to moisture and light. Justification is required in this regard.	Three polyethylene bag used for packing of pellets. Two transparent and one black color bags along with silica gel.
08	Provide information in section 3.2.S.7.1 and 3.2.S.7.2 as CTD per guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is	Firm has submitted information in section 3.2.S.7.1 and 3.2.S.7.2 as CTD per guidance document.

	not in line with the Form 5-F as well as CTD guidance document.	
09	The stability study of Vision Dexlansoprazole pellets performed by Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.	Study performed at lab scale and in chamber they placed sample in pet bottle and for commercial they provide polythene bags and drum which is not possible in pet bottle.
10	Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of Dexlansoprazole pellets wherein the manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarifications required in this regard.	DMF provided by vision pharma
11	Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.	Submitted by the firm.
12	Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be performed, since you have mentioned that pharmaceutical equivalence is not required and then you have also provided a brief report of Dexlansoprazole tablet in which all tests are not performed.	Firm has submitted pharmaceutical equivalence studies against the comparator product manufactured by Weatherfolds pharma.
13	Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter	Firm has submitted results of comparative dissolution profile against the brand leader.
14	submit information in section 3.2.P.3 as per the guidance document which specifies that The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified”	Firm has submitted information in section 3.2.P.3 as per the guidance document.
15	Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1	Firm has submitted information in section 3.2.P.3.2 as per the guidance document.
16	Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "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. Proposals for the reprocessing of materials (if any) shall be justified. Any data t supports this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall	Firm has submitted information in section 3.2.P.3.3 as per the guidance document.

	preferably be continuous; any holding time shall be justified"	
17	Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "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."	Firm has submitted information in section 3.2.P.3.4 as per the guidance document.
18	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has **not** submitted process validation protocols.
19	Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.	Firm has submitted specifications of the drug product in section 3.2.P.5.1.
20	provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarifications required in this regard	Firm has submitted specifications of the drug product in section 3.2.P.5.2.
21	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Firm has **not** submitted complete validation studies of the analytical method of drug product in section 3.2. P.5.3.
22	provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of Dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.	Firm has submitted Batch analysis report of 3 stability batches.
23	Provide COA of the reference standard I working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard	Firm has **not** submitted COA of reference standard / working standard.
24	Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."	Firm has submitted details of container closure system.
25	You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard	Written mistakenly, revised and correct submitted.
26	Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.	Firm has submitted information in section 3.2.P.8.1 and 3.2.P.8.2.
27	justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets	Firm has now submitted dissolution test results at different medium in stability studies.
28	Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.	Firm has submitted specifications and analytical method of drug product.
29	justify the dissolution test in which the acceptance criteria NLT 75% in 5 hours which is against the specifications of innovator's product	Typo mistake Revised COA attached
30	justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter as well as defined by Registration Board in its 293d meeting	Corrected and resubmitted by the firm

31	provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule	Revised COA are submitted by the firm.
32	provide stability study data in a proper se stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and separators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out	Firm has submitted stability data in a proper sequence.
33	submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: • 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 • Documents for the procurement of APl with approval from DRAP (in case of import). • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of both stability chambers	Firm has submitted response against the 6 points checklist as per CTD guidance document.

Decision: Deferred for following observations:

- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established
- Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.
- Provide COA of the reference standard I working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard

Firm's response:

Sr.#	Observation	Reply
1.	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document	Submitted

2.	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.	Firm has submitted revised analytical method verification studies performed by M/s Wezen Pharmaceuticals.
3.	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.
4.	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has submitted revised process validation protocol including the critical steps, sampling plan, and evaluation criteria for the process of capsule filling, sealing and blistering.
5.	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Submitted.
6.	Provide COA of the reference standard in working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.

Decision: Deferred for submission of Pharmaceutical equivalence and Comparative Dissolution Profile (CDP) studies against the innovator's product.

268.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	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. 24364: 03-09-2021
	Details of fee submitted	PKR 50,000/-: 05-01-2021
	The proposed proprietary name / brand name	**NEXIDORE 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Doripenem Monohydrate Eq. to Doripenem…250mg

	Pharmaceutical form of applied drug	Glass vial filled with white to slightly yellowish, off white crystalline powder.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	In house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Finibax Intravenous Infusion 0.25g **(PMDA Japan** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 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, 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. **Firm has not submitted verification studies of analytical method for the testing 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 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	Not performed by the firm
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product.
STABILITY STUDY DATA		
Manufacturer of API	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC,	

	At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA		
API Lot No.	DIPV/B2002002, DPIV/P2001003, DPIV/P2001004		
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.	DN-001	DN-002	DN-003
Batch Size	1200 vials	1200 vials	1200 vials
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	25-04-2020	25-04-2020	25-04-2020
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)	Not applicable.
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. KD/89275/2020/11/33788) issued by FDA Mahrashtra dated 20-10-2020. The certificate is valid till 19-10-2023.
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 Doripenem 3Kg from M/s Kopran Research Laboratories Limited K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA issued by AD (I&E) DRAP field office. The license was issued on 08-04-2020. • Firm has submitted copy of commercial invoice cleared dated 08-04-2020 specifying import of 3Kg doripenem Batch No. DIPV/B2002002, DPIV/P2001003, DPIV/P2001004.
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 two day 24-04-2020 and 25-04-2020.
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 differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP on 3rd September 2021.	

2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Module I is submitted as per CTD guidance document.
3.	Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Revised FPP specifications, method of analysis is submitted.
4.	Justify the use of drug substance having in house specifications while the drug substance specifications are present in JP monograph for "Doripenem hydrate"	Revised specification & method of analysis for Doripenem hydrate as per JP is submitted.
5.	Justify the limit of water from 4.0 – 5.5% in drug substance specifications, while JP monograph specifies the limit from 4.0 – 5.0%.	Drug substance was analyzed using a manufacturer specs and method of analysis at time of development. Moreover, in water contents of drug substance also qualifies the acceptance limit of JP.
6.	Justify why the test for residue on ignition is not performed for the drug substance since it is recommended in JP monograph.	Drug substance was analyzed using a manufacturer specs and method of analysis at time of development where residue on ignition wasn't part of specifications. Now revised specs is submitted.
7.	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."	Specifications & method of analyses from Drug Substance & Drug Product manufacturers is submitted.
8.	Justify the use of a different analytical method for assay testing of drug substance from that specified in JP monograph. The method of drug substance manufacturer is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.	Drug substance was analyzed by using manufacturer's method of analysis at time of development that is why testing conditions differs from that of JP monograph. Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Revised drug substance specification & method of analysis as per JP is submitted.
9.	Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	At time to development we followed in-house method of analysis and submitted analytical method validation. We started following the JP at 12 months' study time-point. Now the Analytical Method Verification Protocol & Report is submitted.
10.	Justify how 260mg of Doripenem Monohydrate eq.to Doripenem is equivalent to 250mg of doripenem as per the label claim.	Molecular weight of Doripenem Monohydrate = 438.52 Molecular weight of Doripenem = 420.50 Factor = 438.52 / 420.50 = 1.04 Equivalent weight ofDoripenem monohydrate for 250mgDoripenem = 250 x 1.04 = 260mg
11.	Justify how the applied drug is to be supplied with 10ml of sodium chloride 0.9% solution, since the innovator product recommends different volume for reconstitution.	10ml of sodium chloride 0.9% solution is for primary reconstitution which will then be further diluted as per requirements.
12.	Justify why pharmaceutical equivalence studies are not performed.	As Nexidore 250mg injection is ready to fill product, and fill weight of 250mg injection is half of 500mg injection. There is no addition of any other contents in the

		formulation so pharmaceutical equivalence study has been done against dorinem 500mg injection by ICI Pakistan.
13.	The process validation protocols does not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.	Revised prospective process validation protocol is submitted.
14.	Justify the drug product specifications section (3.2.P.5.1) with water contents from 4.0% to 5.5% while the JP monograph for the drug product specifies water contents to be 4.0 to 5.0%.	Product specifications has been revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Moreover during stability study the water contents results also complies the JP limits(4-5%)
15.	Justify the limit of assay from 90 – 115% since the JP monograph specifies the assay limit from 95 – 105%.	Product specifications has been revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Moreover during stability study the Nexidore assay results also complies the JP limits(95-105%).
16.	Justify the use of a different analytical method for assay testing of drug product from that specified in JP monograph. The analytical method of drug product is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, total run time and retention time, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.	Drug substance was analyzed by using manufacturer's method of analysis at time of development that is why testing conditions differs from that of JP monograph. Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Revised specification & method of analysis for drug product as per JP is submitted.
17.	Justify the assay preparation step in the assay testing of drug product specifications in which the contents of only 1 vial is taken, justify how the contents taken from only 1 vial can be considered representative of the whole batch.	**No justification is provided by the firm.**
18.	Justify why the test of specificity is not performed during the validation studies of the analytical method of drug product.	Nexidore Injection is ready to fill product. It doesn't contain inactive ingredients, so there wouldn't need the test of specificity during validation studies.Now we are following JP method and analytical method verification study of product is attached with inclusion of specificity.
19.	Provide details of the concentration in mg/ml of different solutions i.e. 50% to 150% used in accuracy and precision testing during validation studies.	Concentration of 50% solution in mg/ml: 125/100 x 1/50 = 0.025mg/ml Concentration of 100% solution in mg/ml: 250/100 x 1/50 = 0.05mg/ml Concentration of 150% solution in mg/ml: 375/100 x 1/50 = 0.075mg/ml **The concentration of standard solution recommended by JP is 0.125mg/ml which is different from the 100% concentration used by the firm.**
20.	Justify why the test of water contents and uniformity of dosage units is not performed in the batch analysis stage.	Both tests have now been performed on drug product
21.	Justify the release of drug product batches on 25-04-2020 after performing test of sterility, since the drug substance was released after testing on 24-04-2020. Justify how the three batches were manufactured and stability studies were being performed within 1 day only.	This is no GMP, non-commercial batch produced for R&D and stability purpose. In case of product development and stability batches the product does not have to go to market normally all test including sterility are started from zero point. Hence in case of product development in order to achieve stability time lines, all test can be started together. Since the product has to stay

		at stability for atleast three months so by the time sterility will come up and if any test fails the results will together come up.
22.	Justify the use of 25ml type-II glass vial for the applied drug product since as per your submission the drug product is to be reconstituted in 10ml normal saline.	It was typo error at time of submission. It is 15mL Type I glass vial.
23.	Justify how the results of initial time point is different at real time and accelerated stability data sheet for batch DN-001 and DN-002.	The product has been tested separately for real time and accelerated time stability that's why their results vary but it is in acceptable range.
24.	Justify how the results of pH and assay of batch DN-001 and DN-002 at initial time point in real time stability studies is exactly same.	It is typo error
25.	You have submitted that all stability batches were manufactured using the drug substance batch No. DPIV/P2001003. For manufacturing of 3 batches each having batch size 1200 vials, approximately 1.87Kg drug substance is required, while as per the clearance documents and commercial invoice 1Kg drug substance of batch number DPIV/P2001003 was imported. Justify how three batches were manufactured using the drug substance having batch number DPIV/P2001003.	Three stability batches were manufactured with 312gm of powder from each of 3 containers. Consumption detail of each API lots for manufacturing of three stability batches are: **Nexidore 250mg Injection (DN-001):** DPIV/B2002002 **Nexidore 250mg Injection (DN-002):** DPIV/P2001003 **Nexidore 250mg Injection (DN-003):** DPIV/P2001004 Firm has not submitted documents for import of these lots of API.
26.	Justify why stability testing was not performed for the drug product at the end of accelerated stability study.	We have already submitted complete accelerated stability study data (6 months). However, attaching again herewith for your review in Annexure 13.we are also providing 9th, 12th, 18th stability study data as per JP method.
27.	Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Submitted by the firm.

Decision of 323rd meeting of Registration Board:

Registration Board after thorough deliberation observed that the firm has not developed the product as per specifications laid down in Japanese Pharmacopoeia. The Board therefore decided not to accept the stability study data and advised the applicant to again perform product development and stability studies of three batches and submit the data on Form 5-F as per the relevant guidance document.

Submission by the firm:

Firm has submitted revised data in which testing has been performed as per JP monograph. The details of revised data is as under:

REVISED DATA SUBMITED BY THE FIRM

Name and address of API manufacturer.	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 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, 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 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	Pharmaceutical equivalence studies are performed with Dorinem Injection 250mg
Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA		
API Lot No.	DIPV/B22010005 DIPV/B22010006 DIPV/B22010007		
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.	DN22-001	DN22-002	DN22-003
Batch Size	900 vials	900 vials	900 vials
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	21-09-2022	21-09-2022	21-09-2022
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)	Meropenem 500mg & 1g Injection (M-296)
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. KD/89275/2020/11/33788) issued by FDA Mahrashtra dated 20-10-2020. The certificate is valid till 19-10-2023.
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 Doripenem 3Kg from M/s Kopran Research Laboratories Limited K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District

		Raigad - 402 302 Maharashtra, INDIA issued by AD (I&E) DRAP field office. The license was issued on 05-09-2022. • Firm has submitted copy of commercial invoice cleared dated 05-09-2022 specifying import of 6Kg Doripenem Batch No. DPIV/P22010005, DPIV/P22010006, DPIV/P22010007.
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 two days.
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:

Decision: Approved with JP 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 shall submit full fee of registration for correction/pre-approval change in stability study data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

269.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	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. 7850: 10-03-2021
	Details of fee submitted	PKR 20,000/-: 05-01-2021
	Proposed proprietary name / brand name	**NEXIDORE 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Doripenem Monohydrate Eq. to Doripenem…500mg
	Pharmaceutical form of applied drug	Glass vial filled with white to slightly yellowish, off white crystalline powder.
	Pharmacotherapeutic Group of (API)	Carbapenem

	Reference to Finished product specifications	In house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	status in reference regulatory authorities	Finibax Intravenous Infusion 0.5g (PMDA Japan Approved)
	For generic drugs (me-too status)	Dorinem Injection 500mg by ICI Pakistan Ltd.
	Name and address of API manufacturer.	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 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, 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 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 for their product against the comparator i.e. Dorinem 500mg injection of ICI Pakistan Ltd Batch No. 0E458 Mfg date 05-2020.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA
API Lot No.	DIPV/B2002002, DPIV/P2001003, DPIV/P2001004
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.	DN-004	DN-005	DN-006
Batch Size	1200 vials	350 vials	350 vials
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	27-04-2020	27-04-2020	27-04-2020
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)	Not applicable.
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. KD/89275/2020/11/33788) issued by FDA Mahrashtra dated 20-10-2020. The certificate is valid till 19-10-2023.
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 Doripenem 3Kg from M/s Kopran Research Laboratories Limited K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA issued by AD (I&E) DRAP field office. The license was issued on 08-04-2020. • Firm has submitted copy of commercial invoice cleared dated 08-04-2020 specifying import of 3Kg doripenem Batch No. DIPV/B2002002, DPIV/P2001003, DPIV/P2001004.
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 partial 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 real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9, since the submitted reference is of Doribex Injection of Janssen cilag international N.V Belgium is currently withdrawn by EMA.	Firm has submitted evidence of approval in PMDA Japan Finibax Intravenous Infusion 0.5g **(PMDA Japan** Approved)
Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Firm has revised the specification as per JP monograph and also submitted fee PKR 7500 for change in specifications. The revised method is still different from JP monograph in following terms • Test of purity as recommended by JP monograph is not added by the firm

	• Mobile phase A and B is used by the firm with run time upto 55 minutes while JP monograph recommends only one typ of mobile phase. • Flow rate set by the firm is 1ml/minute while JP monograph recommends "Adjust so that the retention time of doripenem is about 15 minutes" • System suitability requirements are not provided in the specifications of the firm while it is mentioned in JP monograph. During evaluation of already submitted data by the firm it was identified that firm has used 5 standard chromatograms while JP recommends 6 standards further the JP recommends that theoretical plates should be less than 5000 while the theoretical plates in the submitted data is way above 5000. Further JP monograph recommends a retention time of 15 minutes, while the retention time in firm's data was around 10 minutes.
Justify the use of drug substance having in house specifications while the drug substance specifications are present in JP monograph for "Doripenem hydrate"	Firm has revised the specification as per JP monograph The revised method is still different from JP monograph in following terms • Test of purity as recommended by JP monograph is not added by the firm • Mobile phase A and B is used by the firm with run time upto 55 minutes while JP monograph recommends only one typ of mobile phase. • Flow rate set by the firm is 1ml/minute while JP monograph recommends "Adjust so that the retention time of doripenem is about 15 minutes" • System suitability requirements are not provided in the specifications of the firm while it is mentioned in JP monograph. During evaluation of already submitted data by the firm it was identified that firm has used 5 standard chromatograms while JP recommends 6 standards further the JP recommends that theoretical plates should be less than 5000 while the theoretical plates in the submitted data is way above 5000. Further JP monograph recommends a retention time of 15 minutes, while the retention time in firm's data was around 10 minutes. Further. the analytical method of the drug substance manufacturer is different from JP monograph in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.
Justify the limit of water from 4.0 – 5.5% in drug substance specifications, while JP monograph specifies the limit from 4.0 – 5.0%.	Firm has submitted revised specifications in which limit of water has been changed as per JP monograph. The drug substance specifications still contain the limit of 4 – 5.5%.
Justify why the test for residue on ignition is not performed for the drug substance since it is recommended in JP monograph.	Firm has submitted revised specifications in which residue of ignition has been added as per JP monograph. The drug substance specifications still does not contain this test.
Justify the use of a different analytical method for assay testing of drug substance from that specified in JP monograph. The method of drug substance manufacturer is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability	Firm has submitted that they have analysed the drug substance by using the method of analysis of drug substance manufacturer at the time of development that's why the testing conditions differ from JP monograph. Now, the firm has revised the drug substance specifications as per JP monograph but the revised specifications are not exactly as per JP monograph.

<table>
<tr><td>requirements and acceptance criteria and the formula for calculation of results of assay.</td><td></td></tr>
<tr><td>Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted”. Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.</td><td>Firm has submitted that the testing method of drug substance and drug product is same therefore we performed validation studies on drug product and considered it validated for drug substance as well.
However, the validation studies are performed on analytical method which is entirely different from that specified in JP monograph in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.</td></tr>
<tr><td>Justify how the applied drug is to be supplied with 10ml of sodium chloride 0.9% solution, since the innovator product recommends different volume for reconstitution.</td><td>Firm has submitted that 10ml of normal saline solution is for primary reconstitution which will be further diluted as per requirement.
The details of the innovator / reference product is as follows:
<table>
<tr><td>Particulars</td><td>PMDA</td><td>FDA</td></tr>
<tr><td>Date of initial approval</td><td>25-07-2005</td><td>12-10-2007</td></tr>
<tr><td>Brand name</td><td>Finibax</td><td>Doribax</td></tr>
<tr><td>Current status</td><td>Marketed</td><td>Discontinued</td></tr>
<tr><td>Reconstitution</td><td>contents of 1 bottle and 1 kit dissolved in 100 mL of physiological saline.</td><td>Constitute the 500 mg vial with 10 mL of sterile water for injection or 0.9% sodium chloride injection</td></tr>
</table>
DORIBAX® does not contain a bacteriostatic preservative. Aseptic technique must be followed in preparation of the infusion solution</td></tr>
<tr><td>The process validation protocols does not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.</td><td>Firm has now submitted revised process validation protocols in which vial washing and sterilization time as well as dry heat sterilization time and temperature is mentioned.
However, the firm has directly selected the sterilization temperature and time without providing any protocol how to reach to the final selection of sterilization time and temperature.</td></tr>
<tr><td>Justify the drug product specifications section (3.2.P.5.1) with water contents from 4.0% to 5.5% while the JP monograph for the drug product specifies water contents to be 4.0 to 5.0%.</td><td>Firm has submitted revised sections as per JP monograph</td></tr>
<tr><td>Justify the limit of assay from 90 – 120% since the JP monograph specifies the assay limit from 95 – 105%.</td><td>Firm has submitted revised sections as per JP monograph</td></tr>
<tr><td>Justify the use of a different analytical method for assay testing of drug product from that specified in JP monograph. The analytical method of drug product is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, total run time and retention time, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.</td><td>Firm has submitted that they have analysed the drug substance by using the method of analysis of drug substance manufacturer at the time of development that’s why the testing conditions differ from JP monograph.
Now the firm has revised the drug substance specifications as per JP monograph but the revised specifications are not exactly as per JP monograph.</td></tr>
<tr><td>Justify why the test of specificity is not performed during the validation studies of the analytical method of drug product.</td><td>Nexidore injection is ready to fill product. It does not contain any inactive ingredient so there would not be any need of test of specificity during the validation studies.</td></tr>
<tr><td>Justify why the test of water contents and uniformity of dosage units is not performed in the batch analysis stage.</td><td>Firm has submitted that both tests have been performed now</td></tr>
<tr><td>Justify the release of drug product batches on 27-04-2020 after performing test of sterility, since the drug substance was</td><td>Firm has not submitted any justification.</td></tr>
</table>

<table>
<tr><td>released after testing on 24-04-2020. Justify how the three batches were manufactured and stability studies were being performed within 3 days only.</td><td>Firm has only submitted sterility test reports but no justification is provided.</td></tr>
<tr><td>Justify the use of 25ml type-II glass vial for the applied drug product since as per your submission the drug product is to be reconstituted in 10ml normal saline.</td><td>It was a typo error the actual vials are 15 ml type I glass vial.</td></tr>
<tr><td>Justify the date of initiation of stability studies of 25-4-2020, since batches were released on 27-4-2020.</td><td>It was a typo error the actual date of placement in chamber was 27-04-2020.</td></tr>
<tr><td>You have submitted that all stability batches were manufactured using the drug substance batch No. DPIV/P2001003. For manufacturing of 3 batches each having batch size 1200 vials, approximately 1.87Kg drug substance is required, while as per the clearance documents and commercial invoice 1Kg drug substance of batch number DPIV/P2001003 was imported. Justify how three batches were manufactured using the drug substance having batch number DPIV/P2001003.</td><td>Firm has submitted that we used 3 different lots of API for manufacturing of 3 batches. It was typo error at time of dossier submission. Firm has submitted revised stability data sheets for all batches.
The newly submitted data sheets are different from previously submitted data sheets in following aspects.
<table>
<tr><th>Particulars</th><th>Previously submitted</th><th>Newly submitted</th></tr>
<tr><td colspan="3">Batch No DN-004</td></tr>
<tr><td>0 month date</td><td>25.04.2020</td><td>27.04.2020</td></tr>
<tr><td>3rd month date</td><td>25.07.2020</td><td>28.07.2020</td></tr>
<tr><td>6th month date</td><td>26.10.2020</td><td>27.10.2020</td></tr>
<tr><td>API lot #</td><td>DPIV/P2001003</td><td>DPIV/B2002002</td></tr>
<tr><td colspan="3">Batch No DN-005</td></tr>
<tr><td>0 month date</td><td>25.04.2020</td><td>27.04.2020</td></tr>
<tr><td>3rd month date</td><td>25.07.2020</td><td>28.07.2020</td></tr>
<tr><td>6th month date</td><td>26.10.2020</td><td>27.10.2020</td></tr>
<tr><td>API lot #</td><td>DPIV/P2001003</td><td>DPIV/P2001003</td></tr>
<tr><td colspan="3">Batch No DN-006</td></tr>
<tr><td>0 month date</td><td>25.04.2020</td><td>27.04.2020</td></tr>
<tr><td>3rd month date</td><td>25.07.2020</td><td>28.07.2020</td></tr>
<tr><td>6th month date</td><td>26.10.2020</td><td>27.10.2020</td></tr>
<tr><td>API lot #</td><td>DPIV/P2001003</td><td>DPIV/P2001004</td></tr>
</table>

Firm has also changed the date of testing of 3rd and 6 months as well.
The sterility test and particulate matter was not performed at 3rd or 6th month time point during initially submitted data, however in the newly submitted data sheets the results of both of these tests are also mentioned in the data sheets at 3rd as well as 6th month time point.
</td></tr>
<tr><td>Justify why sterility testing was not performed for the drug product at the end of accelerated stability study.</td><td>Firm has submitted that we have already submitted complete accelerated stability data for 6 months however again we are attaching for your review.
The sterility test and particulate matter was not performed at 3rd or 6th month time point during initially submitted data, however in the newly submitted data sheets the results of both of these tests are also mentioned in the data sheets at 3rd as well as 6th month time point.</td></tr>
<tr><td>Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.</td><td>Firm has submitted that it was submitted along with the dossier.
However, complete audit trail report is not submitted, partial report of testing of only 24-4-2020 and 27-4-2020 is submitted.</td></tr>
<tr><td>Justify how three batches were manufactured on 24-04-2020 in which the sterilization of vials for all the batches was performed collectively on 23-04-2020. Justify how having a single step of sterilization of vials for 3 batches can satisfy the definition of a batch.</td><td>Firm has submitted that three stability batches were manufactured on 24-04-2020 with sterilized vials. Vials are sterilized separately for each batch as these was loaded in sterilizer within a separate box, which are labelled for each batch.
Firm has not submitted any scientific justification for carrying out sterilization of vials collectively for all the three batches.</td></tr>
<tr><td>The submitted BMR’s does not contain any step after the filling of vials justify how the batches were released after the filling of vials including details of physical, analytical and microbiological tests.</td><td>After filling, reconciliation was done for batch consumption rejection and yields in BMRs while analytical and microbiological reports were separately prepared and incorporated in stability files.</td></tr>
</table>

As per the submitted BMR's 624g of drug substance was filled in each batch while the import documents specify that 3 containers each having 1Kg drug substance was imported. Justify how three batches were manufactured.	Stability batches were manufactured with 650gm of powder from each of 3 containers. The details of API use in each batch is as follows: **DN-004:** DPIV/B2002002 **DN-005:** DPIV/P2001003 **DN-006:** DPIV/P2001004

Decision of 313th meeting of Registration Board:

Deferred for following submissions:

- Scientific justification for having drug product specification which is significantly different in terms of test of purity, mobile phase, flow rate / retention time, system suitability requirements, number of injections of the standard solution and theoretical plates from that specified in JP monograph.
- Scientific justification for the analysis of the drug product throughout the stability studies with theoretical plates above 5000, while JP monograph recommends that theoretical plates should be less than 5000.
- Scientific justification for using drug substance having in-house specifications (having completely different analytical method from that recommended in JP monograph) to develop a drug product complying JP pharmacopeia.
- Scientific justification for having limit of water contents from 4.0 – 5.0% while the water contents specified in the drug substance specifications is 4.0 – 5.5%.
- Scientific justification for using a drug substance without any test of residue on ignition, while the same test is recommended in the drug product.
- Justify the performance of verification studies of the drug substance using an analytical procedure which is entirely different from that specified in JP monograph.
- Justify the use of 10ml of 0.9% sodium chloride as diluent, since both USFDA as well as PMDA approved reference products recommends different diluent.
- Justify process validation protocls without defining procedure for validation of sterilization cycle.
- Justify analytical method verification studies of drug product without performing test of specificity.
- Justify the release of drug product batches on 27-04-2020 after performing test of sterility, since the drug substance was released after testing on 24-04-2020. Justify how the three batches were manufactured and stability studies were being performed within 3 days only.
- Justification for re-submission of stability data sheets having different dates for testing at 0, 3rd and 6th month time point and test of sterility and particulate matter for all the batches from that specified in initially submitted stability data sheet.
- Submission of complete audit trail report for all tests performed throughout the stability studies.
- Scientific justification for carrying out sterilization of vials collectively for all the three batches.

Submission by the firm:

Firm has submitted revised data in which testing has been performed as per JP monograph. The details of revised data is as under:

REVISED DATA SUBMITED BY THE FIRM	
Name and address of API manufacturer.	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 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, 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 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	Pharmaceutical equivalence studies are performed against Dorinem Injection 500mg
Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA		
API Lot No.	DIPV/B22010005, DIPV/B22010006, DIPV/B22010007		
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.	DN22-004	DN22-005	DN22-006
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	27-09-2022	27-09-2022	27-09-2022
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)	Meropenen Injection 500mg & 1g (M-296)
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. KD/89275/2020/11/33788) issued by FDA Mahrashtra dated 20-10-2020. The certificate is valid till 19-10-2023.
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 Doripenem 3Kg from M/s Kopran

		Research Laboratories Limited K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA issued by AD (I&E) DRAP field office. The license was issued on 05-09-2022. • Firm has submitted copy of commercial invoice cleared dated 05-09-2022 specifying import of 6Kg Doripenem Batch No. DPIV/P22010005, DPIV/P22010006, DPIV/P22010007.
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 two days
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.
Decision: Approved with JP 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 shall submit full fee of registration for correction/pre-approval change in stability study data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**		

270.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura**
	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) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 10-11-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) 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. 17791: 25-06-2021
	Details of fee submitted	PKR 50,000/-: 09-04-2021
	The proposed proprietary name / brand name	**VARICEF 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……100mg
	Pharmaceutical form of applied drug	Almost pink colored powder having strawberry flavour powder for reconstitution
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	~~USP~~
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	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 Cefspan dry suspension.

	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	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.		
API Lot No.	18CF10035		
Description of Pack (Container closure system)	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.	D-006	D-018	D-022
Batch Size	7500 bottles	7500 bottles	7500 bottles
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	31-01-2019	31-01-2019	31-01-2019
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)	
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, Karachi dated 23-06-2020. The GMP certificate was granted based on inspection dated 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
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	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:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.
- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in USP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.

- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.
- 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."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states 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". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- 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 2020 while the drug product batches were manufactured in 2019.
- Justify how your unit formula containing 0.685gm of drug substance is equivalent to 100mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product Suprax suspension.
- Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservatives without determining the preservative effectiveness.
- The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent / solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on the same formulation.
- The process validation studies have been conducted on three batches having 5000 bottles batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from as low as 7500 and as high as 60,000 bottles. Justification is required in this regard.
- Submit detailed method of analysis of the drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.
- Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.
- Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.
- Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.
- You have provided batch release certificate for batch D-220, D-221 and D-222 in section 3.2.P.5.4 while provided stability study data for batch D-006, D-018 and D-022 in section 3.2.P.8.3. Clarification is required in this regard.
- Provide batch size of Batch D-006 in terms of number of bottles instead of providing batch size in terms of Kg.
- You have submitted that API lot used in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.S.4.4. Justify why data was not submitted in line with the guidance document issued by Registration Board.
- Justify why only 3 chromatographs of the standard solution was run while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Provide raw data sheets showing calculation of the results during the stability studies for all batches.
- Justify why the stability study data is section 3.2.P.8.3 is not submitted as per the guidance document issued by Registration Board.

- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - 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).
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing
- Justify why BMR of different batches is submitted than that for which stability studies were conducted.

Decision of 323rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response by the Firm:

Deficiencies/ Short-comings	Justifications
1. Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received R&I section of DRAP after 7th May 2021.	Firm has submitted the differential fee.
2. Submit valid contract manufacturing agreement between the contract giver and contract acceptor.	Firm has submitted the valid contract.
3. Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Firm has submitted the Module 1 as per CTD guidance document.
4. Submit label claim in Module 1 as per the reference product along with submission of requisite fee.	Firm has submitted the label claim as per reference product.
5. You have mentioned Innovator's Specs in Sec. 1.5.6 in Module 1 while the Drug Product Monograph is available in USP. Revise the Specs. Along with Submission of Requisite Fee.	Firm has explained that Innovator's specs was written mistakenly in Sec 1.5.6. Rest of the dossier is of USP specs already. Corrected Sec 1.5.6 has been attached**.**
6. The drug substance manufacturer has claimed both BP and USP specs. For the assay method, while the submitted method is different from USP in terms of column specs including column length and pore size. Justification is required in this regard.	Drug substance manufacturer used to follow both specs. However, they have performed on USP for our product.
7. The drug substance manufacturer has claimed USP specifications for the Assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required.	Firm has explained that mistake was from the drug substance manufacturer. They have corrected the assay method.
8. Submit data in sec. 3.2.S.4.1 as per the guidance doc. approved by the reg. board which specifies that "copies of drug substance specs and analytical procedure used for routine testing of API by both drug substance and drug product manufacturer is required.	Firm has submitted copies of drug substance specs and analytical procedure used for routine testing of API by both drug substance and drug product manufacturer.
9. Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of registration board which states that the "analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer for both compendial as well as non-drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of analytical method of drug substance.	Firm has submitted analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer
10. Submit data in section 3.2.S.4.4 as per the guidance document approved by registration board which specifies that "provide results analyses of relevant batch(s) of drug substance performed by the drug product manufacturer used during product development and stability studies, along with COA of same batch from API manufacture, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019."	Firm has submitted the results analyses of relevant batch(s) of drug substance performed by the drug product manufacturer used during product development and stability studies, along with COA of same batch from API manufacture.
11. Justify how your Unit Formula Containing 0.685g of Drug Substance is Eq. to 100mg Cefixime base per 5ml After	Firm has submitted the calculation as per reference formulation.

Reconstituted. Further Specify which is the Unit which has been taken as Reference for your Formulation.	
12. Justify the formulation which is different in terms of qualitative composition from that of innovator product suprax suspension.	Firm has submitted the rationale of using excipients in its formulation.
13. Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservative without determining preservative effectiveness.	Firm has justify that sodium citrate has been used as buffering agent for pH control, not the preservative.
14. The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent/solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on same formulation.	Firm has justify that it was typo error in pH. Revised pharmaceutical development document has been submitted.
15. The process validation studies have been conducted on three batches having 5000 bottles batch size. while the batch size of commercial batches for which stability study data is submitted, ranges from as low as 3000 and as high as 10,000 bottles. Justification is required in this regard.	Firm has explained that batch sizes wasn't harmonized for submitted stability batches but from these new submitted batches we have standardize the batch size onward.
16. Submit detailed method of analysis of drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.	Firm has submitted the detailed method of analysis in 3.2.P.5.2
17. Submit exact details of assay preparation since words "reconstitute sample as directed in the labeling" should not be used in the method adopted by firm instead provide details about the exact diluent along with volume in which reconstituted is to be carried out.	Firm has submitted the detailed assay preparation method/
18. Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.	Firm has performed the specificity & precision but not submitted in the dossiers. Now, firm has submitted revised method verification and also explained the concentration of solutions used for accuracy & recovery test.
19. Provide COA of ref std./working std. actually used in the analysis of drug product in section 3.2.P.6	Firm has submitted the COA of working standard used in the analysis of drug product.
20. You have provided batch release certificate for different batches in section 3.2.P.5.4 while the stability study data of different batches is submitted in section 3.2.P.8.3. Clarification is required in this regard.	Firm has submitted the batch release certificates as per stability study batches.
21. Provide batch size of batch D-006 in terms of number of bottles instead of providing batch size in terms of kg.	Firm has submitted the corrected batch size as number of bottles instead of Kg.
22. You have submitted that API lot in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.s.4.4. Justify why data was not submitted in line with guidance document issued by registration board.	Firm has explained that the COA of API lot was not cross checked with the stability batches at that time. Now the aligned COA submitted by the firm.
23. Justify why only 3 Chromatograms of the Std. Solution was run while USP General Chapter <621> Recommends that five replicates of Std. solution should be used for System Suitability Studies.	Firm has submitted the system suitability data as per USP recommendations.
24. Provide raw data sheets showing calculation of the results during the stability studies for all the batches.	Firm has submitted the raw data sheets along with stability data.
25. Justify why the Stability Study Data in Sec. 3.2.P.8.3 is not Submitted as per the Guidance Document Issued by Reg. Board	Firm has explained that the stability documents was not established as per guidance documents. Now, firm submitted the data on correct format.
26. Submit Stability Study data in Sec. 3.2.P.8.3 as per the Checklist Approved by The Reg. Board in its 296th meeting and CTD Guidance Document, Which Includes the Following. • 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) • Compliance Record of HPLC Software 21CFR and Audit Trail Reports on Product Testing.	Firm has submitted that • We have already approved products are Flunaz Dry Susp, Erymac Dry Susp & Ciprobio 125mg & 250 Dry Susp. • Purchase invoice from Saakh pharma provided. • 21CFR compliance of HPLC & Audit trail has been provided

27. Justify why BMR of different batches is submitted than that for which Stability Studies were conducted.	Firm has justify that we did not cross checked the batch numbers in BMRs & Stability data. Now it's been aligned, relevant BMRs.
28. Justify the criteria for selecting batch number and batch size of your product, since different format of batch numbers have been used for different batches, while significant difference in batch size also exist among various production scale batches.	Firm has justified that the stability of concerned product is selected for three consecutive batches of same strength and same dosage form regardless of the time frame. E.g. 03 consecutive batches may run at different time points based on Planned production or need. Since batch numbers are allocated in sequence of a dosage form continuously and hence the batch numbers of the stability batches may differ. E.g. Batches no of Lazma cream 15g may be followed by Lazma Cream 30g and so on. The Batch size of the stability batches of the same product must be of same size According to the validation SOP. However in our old SOP(old batches) this practice was not followed and batches of various batch sizes were used in validation study. Stability of those consecutive batches are selected by QA foe which the lot number of API Utilised is same.

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.**

271.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura**
	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) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 10-11-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) 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. 17790: 25-06-2021
	Details of fee submitted	PKR 50,000/-: 09-04-2021
	The proposed proprietary name / brand name	**VARICEF 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	Almost pink colored powder having strawberry flavour powder for reconstitution
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	~~USP~~
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	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 Cefspan dry suspension.
	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	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.		
API Lot No.	18CF10035		
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.	553	589	597
Batch Size	7500 packs	7500 packs	7500 packs
Manufacturing Date	05-2018	08-2018	09-2018
Date of Initiation	10-05-2018	31-08-2018	28-09-2018
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)	
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, Karachi dated 23-06-2020. The GMP certificate was granted based on inspection dated 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
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	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:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.
- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in USP. Revise the specifications along with submission of requisite fee.

- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.
- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.
- 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."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states 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". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- 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 2020 while the drug product batches were manufactured in 2019.
- Justify how your unit formula containing 1.368gm of drug substance is equivalent to 200mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product Suprax suspension.
- Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservatives without determining the preservative effectiveness.
- The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent / solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on the same formulation.
- The process validation studies have been conducted on three batches having 5000 bottles batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from as low as 3000 and as high as 10,000 bottles. Justification is required in this regard.
- Submit detailed method of analysis of the drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.
- Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.
- Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.
- Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.
- You have provided batch release certificate for different batches in section 3.2.P.5.4 while the stability study data of different batches is submitted in section 3.2.P.8.3. Clarification is required in this regard.
- Provide batch size of Batch D-006 in terms of number of bottles instead of providing batch size in terms of Kg.
- You have submitted that API lot used in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.S.4.4. Justify why data was not submitted in line with the guidance document issued by Registration Board.
- Justify why only 3 chromatographs of the standard solution was run while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Provide raw data sheets showing calculation of the results during the stability studies for all batches.
- Justify why the stability study data is section 3.2.P.8.3 is not submitted as per the guidance document issued by Registration Board.

- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - 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).
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing
- Justify why BMR of different batches is submitted than that for which stability studies were conducted.
- Justify the criteria for selecting batch number and batch size of your product, since different format of batch numbers have been used for different batches, while significant difference in batch size also exist among various production scale batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response by the Firm:

Deficiencies/ Short-comings	Justifications
1. Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received R&I section of DRAP after 7th May 2021.	Firm has submitted the differential fee.
2. Submit valid contract manufacturing agreement between the contract giver and contract acceptor.	Firm has submitted the valid contract.
3. Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Firm has submitted the Module 1 as per CTD guidance document.
4. Submit label claim in Module 1 as per the reference product along with submission of requisite fee.	Firm has submitted the label claim as per reference product.
5. You have mentioned Innovator's Specs in Sec. 1.5.6 in Module 1 while the Drug Product Monograph is available in USP. Revise the Specs. Along with Submission of Requisite Fee.	Firm has explained that Innovator's specs was written mistakenly in Sec 1.5.6. Rest of the dossier is of USP specs already. Corrected Sec 1.5.6 has been attached**.**
6. The drug substance manufacturer has claimed both BP and USP specs. For the assay method, while the submitted method is different from USP in terms of column specs including column length and pore size. Justification is required in this regard.	Drug substance manufacturer used to follow both specs. However, they have performed on USP for our product.
7. The drug substance manufacturer has claimed USP specifications for the Assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required.	Firm has explained that mistake was from the drug substance manufacturer. They have corrected the assay method.
8. Submit data in sec. 3.2.S.4.1 as per the guidance doc. approved by the reg. board which specifies that "copies of drug substance specs and analytical procedure used for routine testing of API by both drug substance and drug product manufacturer is required.	Firm has submitted copies of drug substance specs and analytical procedure used for routine testing of API by both drug substance and drug product manufacturer.
9. Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of registration board which states that the "analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer for both compendial as well as non-drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of analytical method of drug substance.	Firm has submitted analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer
10. Submit data in section 3.2.S.4.4 as per the guidance document approved by registration board which specifies that "provide results analyses of relevant batch(s) of drug substance performed by the drug product manufacturer used during product development and stability studies, along with COA of same batch from API manufacture, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019."	Firm has submitted the results analyses of relevant batch(s) of drug substance performed by the drug product manufacturer used during product development and stability studies, along with COA of same batch from API manufacture.

11. Justify how your unit formula containing 1.368gm of drug substance is equivalent to 200mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.	Firm has submitted the calculation as per reference formulation.
12. Justify the formulation which is different in terms of qualitative composition from that of innovator product suprax suspension.	Firm has submitted the rationale of using excipients in its formulation.
13. Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservative without determining preservative effectiveness.	Firm has justify that sodium citrate has been used as buffering agent for pH control, not the preservative.
14. The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent/solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on same formulation.	Firm has justify that it was typo error in pH. Revised pharmaceutical development document has been submitted.
15. The process validation studies have been conducted on three batches having 5000 bottles batch size. while the batch size of commercial batches for which stability study data is submitted, ranges from as low as 3000 and as high as 10,000 bottles. Justification is required in this regard.	Firm has explained that batch sizes wasn't harmonized for submitted stability batches but from these new submitted batches we have standardize the batch size onward.
16. Submit detailed method of analysis of drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.	Firm has submitted the detailed method of analysis in 3.2.P.5.2
17. Submit exact details of assay preparation since words "reconstitute sample as directed in the labeling" should not be used in the method adopted by firm instead provide details about the exact diluent along with volume in which reconstituted is to be carried out.	Firm has submitted the detailed assay preparation method/
18. Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.	Firm has performed the specificity & precision but not submitted in the dossiers. Now, firm has submitted revised method verification and also explained the concentration of solutions used for accuracy & recovery test.
19. Provide COA of ref std./working std. actually used in the analysis of drug product in section 3.2.P.6	Firm has submitted the COA of working standard used in the analysis of drug product.
20. You have provided batch release certificate for different batches in section 3.2.P.5.4 while the stability study data of different batches is submitted in section 3.2.P.8.3. Clarification is required in this regard.	Firm has submitted the batch release certificates as per stability study batches.
21. Provide batch size of batch D-006 in terms of number of bottles instead of providing batch size in terms of kg.	Firm has submitted the corrected batch size as number of bottles instead of Kg.
22. You have submitted that API lot in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.s.4.4. Justify why data was not submitted in line with guidance document issued by registration board.	Firm has explained that the COA of API lot was not cross checked with the stability batches at that time. Now the aligned COA submitted by the firm.
23. Justify why only 3 Chromatograms of the Std. Solution was run while USP General Chapter <621> Recommends that five replicates of Std. solution should be used for System Suitability Studies.	Firm has submitted the system suitability data as per USP recommendations.
24. Provide raw data sheets showing calculation of the results during the stability studies for all the batches.	Firm has submitted the raw data sheets along with stability data.
25. Justify why the Stability Study Data in Sec. 3.2.P.8.3 is not Submitted as per the Guidance Document Issued by Reg. Board	Firm has explained that the stability documents was not established as per guidance documents. Now, firm submitted the data on correct format.
26. Submit Stability Study data in Sec. 3.2.P.8.3 as per the Checklist Approved by The Reg. Board in its 296th meeting and CTD Guidance Document, Which Includes the Following. 27. Reference of Previous Approval of Applications with Stability Study data of the Firm (if any) 28. Documents for the Procurement of API with Approval from DRAP (In case of Import) 29. Compliance Record of HPLC Software 21CFR and Audit Trail Reports on Product Testing.	Firm has submitted that • We have already approved products are Flunaz Dry Susp, Erymac Dry Susp & Ciprobio 125mg & 250 Dry Susp. • Purchase invoice from Saakh pharma provided. • 21CFR compliance of HPLC & Audit trail has been provided

30. Justify why BMR of different batches is submitted than that for which Stability Studies were conducted.	Firm has justify that we did not cross checked the batch numbers in BMRs & Stability data. Now it's been aligned, relevant BMRs.
31. Justify the criteria for selecting batch number and batch size of your product, since different format of batch numbers have been used for different batches, while significant difference in batch size also exist among various production scale batches.	Firm has justified that the stability of concerned product is selected for three consecutive batches of same strength and same dosage form regardless of the time frame. E.g. 03 consecutive batches may run at different time points based on Planned production or need. Since batch numbers are allocated in sequence of a dosage form continuously and hence the batch numbers of the stability batches may differ. E.g. Batches no of Lazma cream 15g may be followed by Lazma Cream 30g and so on. The Batch size of the stability batches of the same product must be of same size According to the validation SOP. However in our old SOP(old batches) this practice was not followed and batches of various batch sizes were used in validation study. Stability of those consecutive batches are selected by QA foe which the lot number of API Utilised is same.

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.**

272.	**Name, address of Applicant / Importer**	**M/s Sohail Corporation Plot No. 474 Siraj Colony Moosa Lane Karachi.**
	Details of Drug Sale License of importer	**License No:** DHODSK(Drugs)/-433 **Address:** Plot No. 7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No. 42, Karachi **Address of Godown:** NA **Validity:** 19-11-2022. **Status:** Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	Anhui Chengshi Pharmaceutical Co. Ltd. No. 5068, Huaishang Road, Bengbu, Ahui Province China.
	Name, address of manufacturer(s)	Anhui Chengshi Pharmaceutical Co. Ltd. No. 5068, Huaishang Road, Bengbu, Ahui Province China.
	Name of exporting country	China.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (CoPP does not bear any certificate number) dated 29-07-2021 for dexamethasone Sodium Phosphate Injection 4mg/ml. The certificate confirms the free sale status of the product along with GMP status of the manufacturer. The CoPP does not have any issuing authority instead name of the firm is mentioned in place of issuing authority.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized copy of Agency Agreement between Anhui Chengshi Pharmaceutical Co. Ltd. No. 5068, Huaishang Road, Bengbu, Ahui Province China and Sohail Corporation Plot No. 474 Siraj Colony Moosa Lane Karachi. The agreement is valid for 5 years from 1 July

		2020 and specifies DEXAMETHASONE Sodium Phosphate Injection 4mg/ml.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	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 30797: 19-11-2021
	Details of fee submitted	PKR 100,000/-: 07-04-2021 PKR 50,000/-: 07-06-2021
	The proposed proprietary name / brand name	**DEXAMETHASONE Sodium Phosphate Injection 4mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml ampoule contains: Dexamethasone sodium phosphate ……..4mg
	Pharmaceutical form of applied drug	Clear colourless solution in glass ampoule
	Pharmacotherapeutic Group of (API)	Glucocorticoid
	Reference to Finished product specifications	USP
	Proposed Pack size	4mg/1ml glass ampoule
	Proposed unit price	No submitted by the firm
	The status in reference regulatory authorities	DBL DEXAMETHASONE SODIUM PHOSPHATE INJECTION 4mg/1mL **(TGA** Approved).
	For generic drugs (me-too status)	Dexonil 4mg Injection by Vision pharma (Reg#037570)
	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 Xianju Pharmaceutical Co. Ltd. No. 1 Xian Yao Road, 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, 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 / 60% RH. The stability study data is till 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 pharmaceutical equivalence against following products: • Dexamethasone sodium phosphate injection of Aspen Pharma Trading Limited. • Dexamethasone sodium phosphate injection of Xinxiang Changle Pharmaceutical Co. Ltd. • Dexamethasone sodium phosphate injection of Zhejiang Xianju Pharmaceutical Co. Ltd. • Dexamethasone sodium phosphate injection of Shanghai Tongyong Pharmaceutical Co Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Glass ampoule in colour printed box
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 36 months at 30±2°C, 75±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC:

Sr. No	Observations communicated	Response by the firm
1.	The label claim of the innovator's product specifies that each ml ampoule contains dexamethasone sodium phosphate equivalent to 4 mg of dexamethasone phosphate, while your label claim and CoPP specifies that the injection contains 4mg dexamethasone sodium phosphate per ml ampoule.	In China, the content of dexamethasone sodium phosphate injection is shown by the dexamethasone sodium phosphate instead of dexamethasone phosphate. So the label and CoPP specify content of dexamethasone sodium phosphate injection by the dexamethasone sodium phosphate. In fact, the dexamethasone sodium phosphate injection 4mg/1ml is same with the innovator's product which specifies that each ml ampoule contains dexamethasone sodium phosphate equivalent to 4mg of dexamethasone phosphate. Please reference the following explains for details. In the USP "DEFINITION": Dexamethasone Sodium Phosphate Injection is a sterile solution of Dexamethasone Sodium Phosphate in Water for Injection. It contains NLT 90.0% and NMT 115.0% of the labeled amount of dexamethasone phosphate ($C_{22}H_{30}FO_8P$), present as the disodium salt. The molecular weight of $C_{22}H_{30}FO_8P$ is 472.4. The molecular weight of $C_{22}H_{28}FNa_2O_8P$ is 516.4. For our product: the labeled amount is 4mg/ml of Dexamethasone Sodium Phosphate equivalent to 3.7mg/ml of dexamethasone phosphate. According to the USP standard, the qualified content range of dexamethasone phosphate is 3.33mg/ml to 4.26mg/ml. For innovator's product: the labeled amount is 4mg/ml of dexamethasone phosphate. According to the USP standard, the qualified content range of dexamethasone phosphate is 3.6mg/ml to 4.6mg/ml.

		So we just have to ensure that the content of our product is within this range of dexamethasone phosphate 3.60mg/ml-4.26mg/ml. Our product will be same same with the innovator's product. And we will clearly indicate content of dexamethasone phosphate (3.60mg/ml-4.26mg/ml) in our drug product leaflet.
2.	Master formulation, composition and CoPP specifies that each vial contains 4mg dexamethasone sodium phosphate while as per innovator's product each vial contains 4mg of dexamethasone phosphate. Clarification is required in this regard.	In China, the content of dexamethasone sodium phosphate injection is shown by the dexamethasone sodium phosphate instead of dexamethasone phosphate. So the label and CoPP specify content of dexamethasone sodium phosphate injection by the dexamethasone sodium phosphate. In fact, the dexamethasone sodium phosphate injection 4mg/1ml is same with the innovator's product which specifies that each ml ampoule contains dexamethasone sodium phosphate equivalent to 4mg of dexamethasone phosphate. Please reference the following explains for details.
3.	Provide report of validation studies of the analytical method of drug product since you have only submitted brief summary.	The analytical procedure of the Dexamethasone Sodium Phosphate injection 4mg/1ml is according to the USP. so we only do the assay validation . the summary is as follows. The detail information please check the "Attachment 2 -- Validation of Analytical Procedures of Dexamethasone Sodium Phosphate 4mg/1ml".
4.	Address of the applicant mentioned in module 1 and also specified in agency agreement is "*Sohail Corporation Plot No. 474 Siraj Colony Moosa Lane Karachi"* while the address of the firm as per Drug Sale License is "*Sohail Corporation Plot No. 7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No. 42, Karachi".* Clarification is required in this regard.	The address of applicant (Sohail Corporation) has changed. As this is our previous address Sohail Corporation Plot No.474 Siraj Colony Moosa Lane, Karachi-Pakistan" Now the current address is "Sohail Corporation Plot No.7, SR-5, Serai Quarters (Techo City) WH-42, Ware House No. 42, Karachi"
5.	The submitted CoPP does not bear any certificate number, moreover issuing authority of the CoPP is mentioned as Anhui Chengshi Pharmaceutical Co. Ltd which is the product license holder and manufacturer in China. Clarification is required in this regard.	First, our COPP is notarized by the Notary Office, and then certified by the Ministry of Foreign Affairs and the Pakistan Consulate. The Notary Office is established in accordance with the 《 Notary Law of the People's Republic of China》. The notary office is a non-profit verification institution that independently exercises the notarization function and assumes civil liability. When the Notary Office notarizes the COPP, the Notary Office will first communicate with the corresponding regulatory authorities to verify whether the manufacturer has the qualification and record to produce and sell the product. If the manufacturer has the corresponding qualification and record and the situation is true, the corresponding COPP will be notarized and the notarial certificate will be issued. Then the Ministry of Foreign Affairs verified the notarial certificate, and if the notarial certificate is true, the notarial certificate will be proved. Finally, the corresponding consulate will verify the notarial certificate that have been certified by the Ministry of Foreign Affairs. And we promise to keep renewing the COPP. As soon as we get the renewed COPP, we will send it to you.

Decision: Deferred for following submissions:

- **Clarification of the label claim and master formulation of the applied product in line with the innovator's product formulation.**
- **Full fee of registration for change in the address of the importer / applicant.**
- **Afresh Sole agency agreement in name of the applicant with new address.**
- **Clarification since the submitted CoPP does not bear any certificate number, and the issuing authority of the CoPP is mentioned as Anhui Chengshi Pharmaceutical Co. Ltd which is the product license holder and manufacturer in China**

Case no. 01 Registration applications of newly granted DML or New section (Human)

a. New DML

M/s Nagarsons Pharmaceutical (Pvt) Ltd **. (New DML)**

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

Sr. No	Section	Molecules for consideration in 327th meeting	Products for consideration in 327th meeting
1	Tablet (General)	01	02

273.	Name, address of Applicant / Marketing Authorization Holder	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zone, Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries 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. 5894 dated 02-03-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 543749515652
	The proposed proprietary name / brand name	Relpride Tablet 25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains; Levosulpiride ……. 25 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Propulsive/Prokinetics
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levosulpiride Aristo 25 mg tablets, AIFA Italy approved.

	For generic drugs (me-too status)	Sulvoric 25mg Tablet of M/s High-Q Reg. No.070484
	GMP status of the Finished product manufacturer	New license granted on 19th Feburary 2021.
	Name and address of API manufacturer.	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad 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, 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)	Official monograph of Levosulpiride is not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubility's, 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	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: (ALC/LSP/170203, ALC/LSP/170204, ALC/LSP/170205)
	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 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	

STABILITY STUDY DATA	
Manufacturer of API	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad Gujrat, India.
API Lot No.	BLEVS210029
Description of Pack (Container closure system)	Alu-Alu blister packed
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.	T001	T002	T003
Batch Size	2000	2000	2000
Manufacturing Date	01-22	01-22	01-22
Date of Initiation	05-01-22	05-01-22	05-01-22
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# S-GMP/20102297 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. issued on 22-10-2020 and valid until 21-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy form 5 and invoice (invoice# AB/I/00101/21-22) dated: 01-09-2021 attested by DRAP Islamabad dated: 13-9-2021 specifying import of 10Kg Levosulpiride (Batch# BLEVS210029)
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)	Not submitted

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
3.	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
4.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
6.	3.2.P.2.2.1	• Justification shall be submitted for not carrying the CDP against the innovator's brand • Details and picture/image/ snapshot of product against which Pharmaceutical Equivalence and CDP conducted. • 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution.

		• As per Innovator product in CDP percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8 while as per your CDP data higher than 85% at 30 minutes. Justification is required.
7.	3.2.P.5.1	Applied formulations in section 1.5.6 are Innovator while in this section USP specifications are clamed. Clarify.
8.	3.2.P.5.3	Analytical method verification submitted while product is not available in any pharmacopeia.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP as submitted Commercial Invoice is not in readable form.. • Batch size is not mentioned • 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: Registration Board deferred the case for submission of reply to the above cited shortcomings.

274.	Name, address of Applicant / Marketing Authorization Holder	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zone, Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries 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. 5895 dated 02-03-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 91709832
	The proposed proprietary name / brand name	Relpride Tablet 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains; Levosulpiride ……. 50 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Propulsive/Prokinetics
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Sulvoric 50mg Tablet of M/s High-Q Reg. No.070485
	GMP status of the Finished product manufacturer	New license granted on 19th Feburary 2021.
	Name and address of API manufacturer.	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad 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, 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)	Official monograph of Levosulpiride is not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubility's, 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	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: (ALC/LSP/170203, ALC/LSP/170204, ALC/LSP/170205)
	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 is established against the brand that is LEVOPRAID 50 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., 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	

STABILITY STUDY DATA

Manufacturer of API	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad Gujrat, India.		
API Lot No.	BLEVS210029		
Description of Pack (Container closure system)	Alu-Alu blister packed		
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.	T004	T005	T006

Batch Size	2500/2000	2500/2000	2500/2000
Manufacturing Date	01-22	01-22	01-22
Date of Initiation	05-01-22	05-01-22	05-01-22
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# S-GMP/20102297 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. issued on 22-10-2020 and valid until 21-10-2022.
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.	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)	Not submitted

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
3.	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
4.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
6.	3.2.P.2.2.1	• Justification shall be submitted for not carrying the CDP against the innovator's brand • Details and picture/image/ snapshot of product against which Pharmaceutical Equivalence and CDP conducted. • 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution. • As per Innovator product in CDP percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8 while as per your CDP data higher than 85% at 30 minutes. Justification is required.
7.	3.2.P.5.1	Applied formulations in section 1.5.6 are Innovator while in this section USP specifications are clamed. Clarify.
8.	3.2.P.5.3	Analytical method verification submitted while product is not available in any pharmacopeia.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP.(Clear Commercial Invoice).

		• Batch size is not mentioned • 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: Registration Board deferred the case for submission of reply to the above cited shortcomings.

b. New/Additional section(s)

M/s PDH Laboratories Pvt Ltd. **(New Section)**
CLB in its 285th meeting held on 17th & 18th March 2022, has approved the following 01 additional sections of M/s PDH Laboratories Pvt Ltd.

1.Oral liquid Section (General) Additional

Sr. No	Section	Molecules for consideration in 327th meeting	Products for consideration in 327th meeting
1	Oral liquid Section (General)	01	02

275.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura 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. 3222 dated 03-02-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 708047908
	The proposed proprietary name / brand name	Temol Suspension 120mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Paracetamol…….120mg
	Pharmaceutical form of applied drug	Clear, viscous liquid light orange to orange colour
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's x 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 120 mg/5 ml Oral Suspension by Pinewood Laboratories Limited, Ireland of MHRA approved.
	For generic drugs (me-too status)	Calpol Pediatric Suspension of M/s GlaxosmithKline Pakistan. No.000354
	GMP status of the Finished product manufacturer	Copy of cGMP certificate on the basis of Evaluation conducted on 04-01-2022 and valid for two years.

	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, 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, 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)	Official monograph of Paracetamol(Actaminophen) is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, 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	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (21GN60001, 21GN60002, 21GN60003)
	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 is established against the brand that is Calpol Suspension by M/s GSK Batch # 372R by performing quality tests (description, Identification, pH, Deliverable Volume, Viscosity, Microbial Enumeration, Assay)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.
API Lot No.	21GN60187
Description of Pack (Container closure system)	Clear, viscous liquid light orange to orange colour sweet in taste filled in ambered glass bottle of USP type III sealed with Aluminium cap, neatly labelled and packed in a unit carton with insertion of 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, 9, 12 (Months)

Batch No.	T-006	T-007	T-008
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	10-12-2021	10-12-2021	10-12-2021
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.	Copy of cGMP certificate on the basis of evaluation conducted on 07-10-2022 and valid for 02 years.
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.	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:

S.No	Section	Shortcomings Communicated
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.2	In Assay final concentrations is 0.01mg/ml while 96 mg of paracetamol from oral suspension taken. Clarify how from 96mg 0.01mg/ml concentration prepared.
4.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
5.	3.2.P.8	Purchase Documents for Paracetamol. Compliance Record of HPLC software 21CFR & audit trail reports on product testing

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

276.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura 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. 7379 dated 14-03-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 3924666116
	The proposed proprietary name / brand name	Temol DS Suspension 250mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Paracetamol…….250mg
	Pharmaceutical form of applied drug	Clear, viscous liquid light orange to orange colour
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's x 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 250 mg/5 ml Oral Suspension by Pinewood Laboratories Limited, Ireland of MHRA approved.
	For generic drugs (me-too status)	Calpol 6 plus Suspension of M/s GlaxosmithKline Pakistan. No.000354
	GMP status of the Finished product manufacturer	Copy of cGMP certificate on the basis of Evaluation conducted on 04-01-2022 and valid for two years.
	Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, 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, 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)	Official monograph of Paracetamol(Actaminophen) is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, 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	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (21GN60001, 21GN60002, 21GN60003)
	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 is established against the brand that is Calpol 6 Plus Suspension by M/s GSK Batch # 372R by performing quality tests (description, Identification, pH, Deliverable Volume, Viscosity, Microbial Enumeration, Assay)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.		
API Lot No.	21GN60187		
Description of Pack (Container closure system)	Clear, viscous liquid light orange to orange colour sweet in taste filled in ambered glass bottle of USP type III sealed with Aluminium cap, neatly labelled and packed in a unit carton with insertion of 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.	T-007	T-008	T-009
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	20-06-2022	22-06-2022	24-06-2022
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 cGMP certificate on the basis of evaluation conducted on 07-10-2022 and valid for 02 years.
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.	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:

S.No	Section	Shortcomings Communicated
1.	3.2.S.4.3	In Drug substance Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3

		replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
4.	3.2.P.8	Purchase Documents for Paracetamol. Compliance Record of HPLC software 21CFR & audit trail reports on product testing
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		

Agenda of Evaluator PEC-IX

277.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section
	Brand Name + Dosage Form + Strength	PAROZON 12.5mg control release tablet
	Composition	Each film coated control release tablet contains; Paroxetine HCl eq. to Paroxetine USP……12.5mg
	Diary No. Date of R & I & fee	Dy. No. 15502 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0826908 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB05
	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	PAXIL CR, Paroxetine hydrochloride (eq to base: 12.5mg, 25mg, 37.5mg) tablet extended release. USFDA Approved.
	Me-too status	Seroxat CR tablet 12.5mg Reg. No. 043058 M/s GSK Karachi.
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
278.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section
	Brand Name + Dosage Form + Strength	RELDIC 100mg Tablet
	Composition	Each tablet contains; Diclofenac sodium……100mg
	Diary No. Date of R & I & fee	Dy. No. 15503 dated 07.03.2019. Fee paid Rs. 20,000/-

		vide Slip No. 0826907 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Acetic acid derivatives and related substances ATC Code: M01AB05
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	10's, 20's, 100's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Voltral 100mg SR Tablets Reg. No. 021526 M/s Novartis Pharma Karachi.
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.
	Remarks of the Evaluator	Evidence of product approval in RRA 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.	
279.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Ebastizon 10mg Tablet
	Composition	Each film coated tablet contains; Ebastine…….10mg
	Diary No. Date of R & I & fee	Dy. No. 15500 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0760244 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX22
	Type of Form	Form-5
	Finished product Specification	JP Specifications.
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ebastine Viatris 10mg film-coated tablet ANSM, France Approved.
	Me-too status	Mestin 10mg Tablet Reg. No. 094054 M/s Metro Pharmaceuticals Rawat.
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.
	Remarks of the Evaluator	
	Decision: Duplicate with case at S. No. 80.	
280.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section
	Brand Name + Dosage Form + Strength	DOMPIZON 10mg Tablet
	Composition	Each tablet contains; Domeperidone as maleate…….10mg
	Diary No. Date of R & I & fee	Dy. No. 15499 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0760249 dated 05-03-2019, endorsed on

		07.03.2019.
	Pharmacological Group	Propulsives ATC Code: A03FA03
	Type of Form	Form-5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	DOMPERIDONE APOTEX domperidone (as maleate) 10mg tablets TGA Approved
	Me-too status	Domlis 10mg Tablet by M/s Lisko Pakistan (Reg#094897)
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved	
281.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section
	Brand Name + Dosage Form + Strength	PIRON 20mg Tablet
	Composition	Each tablet contains; Piroxicam beta cyclodextrin equivalent to Piroxicam..20mg
	Diary No. Date of R & I & fee	Dy. No. 15504 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0826913 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Oxicams ATC Code: M01AC01
	Type of Form	Form-5
	Finished product Specification	Not mentioned.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Applied product is not effervescent. BREXIN 20 MG EFFERVESCENT TABLET ANSM FRANCE APPROVED.
	Me-too status	Straza Tablet Reg. No. 096316 M/s Asian Continental Karachi.
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Evidence of approval of applied formulation in RRA of is required
	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.** • **Reference of finished product specifications**	
282.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section

	Brand Name + Dosage Form + Strength	Metrozon 400mg Tablet
	Composition	Each film coated tablet contains; Metronidazole…….400mg
	Diary No. Date of R & I & fee	Dy. No. 15501 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0760246 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Agents Against Amoebiasis And Other Protozoal Diseases, Nitroimidazole Derivatives. ATC Code: P01AB01
	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	METRONIDAZOLE 400 MG FILM-COATED TABLETS - PL 43461/0068 MHRA Approved
	Me-too status	Flagyl Tablets 400mg Reg. No. 000827
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
283.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Lowpress 50mg Tablet
	Composition	Each film coated tablet contains; Losartan potassium……..50mg
	Diary No. Date of R & I & fee	Dy. No. 17037 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849832 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain ATC Code: C09CA01
	Type of Form	Form-5
	Finished product Specification	Not mentioned. (monograph available in USP)
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LOSARTAN POTASSIUM 50 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Lo-K Tablets 50mg Reg. No. 050968 M/s Leads Pharma islamabad.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved with USP Specifications. 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 07-05-2021, before issuance of registration letter.	

284.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	ARIPIZOLE 15mg Tablet
	Composition	Each film coated tablet contains; Aripiprazole……..15mg
	Diary No. Date of R & I & fee	Dy. No. 17036 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786687 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX12
	Type of Form	Form-5
	Finished product Specification	**Hi-Med's Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Aripiprazole 5, 10, 15 and 30 mg tablets (aripiprazole) - PL 24837/0050-0053; UK/H/5676/001-004/DC MHRA Approved.
	Me-too status	Mactril tablet 15mg Reg. No. 067735 M/s Wilshire Laboratories Lahore.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
285.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	FINAMED 5mg Tablet
	Composition	Each film coated tablet contains; Finasteride……..5mg
	Diary No. Date of R & I & fee	Dy. No. 17032 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0832246 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Testosterone-5-alpha reductase inhibitors ATC code: G04CB01
	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	Finasteride 5mg Film-Coated Tablets - PL 21300/0019 MHRA Approved.
	Me-too status	Prosnom Tablet 5mg Reg. No. 024677 M/s Pharmatec Pakistan.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	

	Decision: Approved.	
286.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	FLUFEN 100mg Tablet
	Composition	Each film coated tablet contains; Flurbiprofen……..100mg
	Diary No. Date of R & I & fee	Dy. No. 17023 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0832247 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Propionic acid derivatives ATC Code: M01AE09
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (Available in BP&USP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Flurbiprofen 100mg Tablet Oral USFDA Approved.
	Me-too status	Ansaid 100mg Tablet Reg. No. 012299 M/s Pfizer Pakistan.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Reference of finished product specifications is required.
	Decision: Approved with USP specifications. 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 07-05-2021, before issuance of registration letter.	
287.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
	Brand Name + Dosage Form + Strength	RIBAMED 200mg Capsule
	Composition	Each capsule contains; Ribavirin……200mg
	Diary No. Date of R & I & fee	Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 081x944 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antivirals for treatment of HCV infections ATC Code: J05AP01
	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	Ribavirin 200 mg capsules, hard MHRA Approved.
	Me-too status	Anti-C cap 200mg Reg. No. 029547 M/s Werrick Islamabad.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	

	Decision: Approved.	
288.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MELOCAM 7.5mg Chewable Tablet
	Composition	Each chewable tablet contains; Meloxicam…….7.5mg
	Diary No. Date of R & I & fee	Dy. No. 17054 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849822 dated 27-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Oxicams ATC code: M01AC06
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified for chewable tablet.
	Me-too status	Could not be verified for chewable.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Evidence of me-too and evidence of approval of applied formulation (chewable) in RRA is required.
	Deferred for following: • **Reference of finished product specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
289.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MELOCAM 15mg Chewable Tablet
	Composition	Each chewable tablet contains; Meloxicam…….15mg
	Diary No. Date of R & I & fee	Dy. No. 17055 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849823 dated 27-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Oxicams ATC code: M01AC06
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified for chewable tablet.
	Me-too status	Could not be verified for chewable.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.

	Remarks of the Evaluator	• Reference of finished product specifications is required. • Evidence of me-too and evidence of approval of applied formulation (chewable) in RRA is required.
	Decision: Deferred for following: • **Reference of finished product specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
290.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MELOCAM 7.5mg Tablet
	Composition	Each film coated tablet contains; Meloxicam…….7.5mg
	Diary No. Date of R & I & fee	Dy. No. 17052 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849830 dated 27-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Oxicams ATC code: M01AC06
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (Available in BP & USP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MELOXICAM 7.5 MG TABLETS - PL 14251/0097 MHRA Approved.
	Me-too status	Xobix 7.5mg Tablet Reg. No. 023928 M/s Hilton Pharma Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • The innovator product is uncoated, whereas applied formulation is of coated tablet. Correction along with fee of Rs. 7500/- is required.
	Decision: Approved with USP Specifications and following label; **"Each tablet contains;** **Meloxicam…….7.5mg"** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications and description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
291.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MELOCAM 15mg Tablet
	Composition	Each film coated tablet contains; Meloxicam…….15mg
	Diary No. Date of R & I & fee	Dy. No. 17053 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849829 dated 27-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Oxicams

		ATC code: M01AC06
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (Available in BP & USP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Meloxicam 15mg Tablets MHRA Approved.
	Me-too status	Xobix 15mg Tablet Reg. No. 023929 M/s Hilton Pharma Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • The innovator product is uncoated, whereas applied formulation is of coated tablet. Correction along with fee of Rs. 7500/- is required.
	Decision: Approved with USP Specifications and following label; **"Each tablet contains;** **Meloxicam…….15mg"** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications and description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
292.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
	Brand Name + Dosage Form + Strength	PREGAB 50mg Capsule
	Composition	Each capsule contains; Pregabalin…….50mg
	Diary No. Date of R & I & fee	Dy. No. 17049 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0832249 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Lyrica® 50 mg hard capsules MHRA Approved.
	Me-too status	Gabica 50 mg Capsule Reg. No. 048725 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications. **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 07-05-2021, before issuance of registration letter.**	
293.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section

	Brand Name + Dosage Form + Strength	PREGAB 75mg Capsule
	Composition	Each capsule contains; Pregabalin…….75mg
	Diary No. Date of R & I & fee	Dy. No. 17056 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0832243 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Pregabalin Noumed 25, 50, 75, 100, 150, 200, 225 and 300mg Capsules, hard (pregabalin) - PL 44041/0065-0072 MHRA Approved.
	Me-too status	Gabica 75 mg Capsule Reg. No. 047365 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications. **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 07-05-2021, before issuance of registration letter.**	
294.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
	Brand Name + Dosage Form + Strength	PREGAB 300mg Capsule
	Composition	Each capsule contains; Pregabalin…….300mg
	Diary No. Date of R & I & fee	Dy. No. 17051 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0832242 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Pregabalin Noumed 25, 50, 75, 100, 150, 200, 225 and 300mg Capsules, hard (pregabalin) - PL 44041/0065-0072 MHRA Approved.
	Me-too status	Gabica 300 mg Capsule Reg. No. 047368 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	

	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 07-05-2021, before issuance of registration letter.	
295.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Levomed 5mg tablet
	Composition	Each film coated tablet contains; Levocetrizine……5mg
	Diary No. Date of R & I & fee	Dy. No. 170410 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786694 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE, Piperazine derivatives. ATC Code: R06AE09
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (available in USP)**
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Levocetirizine Dihydrochloride 5 mg Film-coated Tablets MHRA Approved.
	Me-too status	T-Day Tablet 5 mg Reg. No. 083964 M/s GlaxoSmithKline Petaro Roard.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Label claim does not mention dihydrochloride salt. Revision as per innovator product along with full fee (i.e. Rs.30,000/-) is required.
	Decision: Approved with USP Specifications and following label; **"Each film coated tablet contains;** **Levocetrizine as dihydrochloride……5mg "** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
296.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Levomed 10mg tablet
	Composition	Each film coated tablet contains; Levocetrizine……10mg
	Diary No. Date of R & I & fee	Dy. No. 17046 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786695 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE, Piperazine derivatives. ATC Code: R06AE09
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (available in USP)**
	Pack size & Demanded Price	14's. As per SRO.

	Approval status of product in Reference Regulatory Authorities	Could not be verified for 10mg strength
	Me-too status	L-Citriza 10mg Tablets Reg. No. 080407
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Evidence of approval of applied formulation in RRA is required.
	Decision: Deferred for following: • **Reference of finished product specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
297.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Levamed 250mg tablet
	Composition	Each film coated tablet contains; Levetiracetam……250mg
	Diary No. Date of R & I & fee	Dy. No. 17047 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786698 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14
	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	LEVETIRACETAM RIVOPHARM 250 MG FILM-COATED TABLETS - PL 33155/0025 MHRA Approved.
	Me-too status	Vicet Tablet 250mg Re. No. 061773 M/s Martin Dow Ltd. Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved.	
298.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Levamed 500mg tablet
	Composition	Each film coated tablet contains; Levetiracetam……500mg
	Diary No. Date of R & I & fee	Dy. No. 17048 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786699 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14

	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	LEVETIRACETAM RIVOPHARM 500 MG FILM-COATED TABLETS - PL 33155/0026 MHRA Approved.
	Me-too status	Vicet Tablet 500mg Re. No. 061774 M/s Martin Dow Ltd. Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved.	
299.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	DOMMED 10mg Tablet
	Composition	Each film coated tablet contains; Domeperidone maleate 12.72 mg eq to domeperidone……..10mg
	Diary No. Date of R & I & fee	Dy. No. 17038 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786693 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Propulsives ATC code: A03FA03
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	DOMPERIDONE ARROW 10 mg film-coated tablet ANSM France approved Domperidone 10 mg Tablets (uncoated) Each tablet contains 12.72 mg of Domperidone maleate equivalent to 10 mg Domperidone MhRA Approved.
	Me-too status	Motilium Tablet 10mg (Domeperidone HCl 10mg) Reg No. 006526 M/s Aspin Pharma (Pvt.) ltd. Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• The product approved by ANSM France does not mention maleate salt, whereas product approved in MHRA is uncoated. Further, me-too is approved as HCl salt. • Reference of finished product specifications is required.
	Decision: Deferred for following; • **Reference of finished product specifications.** • **Revision of formulation as per innovator product along with submission of requisite fee.**	

300.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	BHIS 16mg Tablet
	Composition	Each Film coated tablet contains; Betahistine……16mg
	Diary No. Date of R & I & fee	Dy. No. 17038 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849824 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	ANTIVERTIGO PREPARATIONS ATC Code: N07CA01
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	BETAHISTINE DIHYDROCHLORIDE DAWA 16MG TABLETS 16 MG TABLETS - PL 30684/0298 MHRA Approved
	Me-too status	BHS Tablet 16mg, Rotex Pharma, Reg. No. 100819
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required. • The innovator uses dihydrochloride salt whereas in applied formulation base is used. Justification or correction along with fee of Rs. 30,000/- is required.
	Decision: Approved with innovator's specifications and following label; **Each tablet contains;** **Betahistine dihydrochloride……16mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
301.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	LOPRIDON 2mg Tablet
	Composition	Each film coated tablet contains; Iloperidone……2mg
	Diary No. Date of R & I & fee	Dy. No. 17043 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849825 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX14
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.

	Approval status of product in Reference Regulatory Authorities	FANAPT (iloperidone 1mg, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg) uncoated Tablets USFDA Approved.
	Me-too status	Ereden 2mg Tablet Reg. No. 083307 M/s Martin Dow Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required along with fee of Rs. 7500/-
	Decision: Approved with innovator's specifications and following label; **Each tablet contains;** **Iloperidone……2mg** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications and description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
302.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	LOPRIDON 4mg Tablet
	Composition	Each film coated tablet contains; Iloperidone……4mg
	Diary No. Date of R & I & fee	Dy. No. 17044 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900220 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX14
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	FANAPT (iloperidone 1mg, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg) uncoated Tablets USFDA Approved.
	Me-too status	Ereden 4mg Tablet Reg. No. 083306 M/s Martin Dow Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required along with fee of Rs. 7500/-
	Decision: Approved with innovator's specifications and following label; **Each tablet contains;** **Iloperidone……4mg**	

	The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications and description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
303.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Sparomed 100mg Tablet
	Composition	Each film coated tablet contains; Sparfloxacin……..100mg
	Diary No. Date of R & I & fee	Dy. No. 17030 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849831 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA09
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Spar-Cin 100mg Tablet Reg. No. 036762 M/s Fozan Pharmaceuticals Peshawar.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Evidence of approval of applied formulation in RRA is required.
	Decision: Deferred for following: • **Reference of finished product specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
304.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	OSAMED 830mg Tablet
	Composition	Each film coated tablet contains; Ossein mineral complex……830mg
	Diary No. Date of R & I & fee	Dy. No. 17042 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786692 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Calcium and multimineral
	Type of Form	Form-5
	Finished product Specification	**Not Mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Osteoget Tablet Reg. No. 063417 M/s Global Pharma Islamabad.

	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Evidence of approval of applied formulation in RRA is required.
	Decision: Deferred for following: • **Reference of finished product specifications.** • **Evidence of of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
305.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	FEXOMED 60mg/120mg Tablet
	Composition	Each film coated tablet contains; Fexofenadine HCl……60mg Pseudoephedrine HCl…….120mg
	Diary No. Date of R & I & fee	Dy. No. 17025 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849833 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	pseudoephedrine, combinations ATC Code: R01BA52
	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	ALLEGRA-D Fexofenadine hydrochloride and pseudoephedrine hydrochloride caplets (Sustained-Release) Caplets, 60 mg & 120 mg, Oral. The product approved by Health Canada is a Sustained release formulation.
	Me-too status	Fexo-D Tablets Reg. No. 031607 M/s Hilton Pharma (Pvt.) Ltd.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Evidence of approval of applied formulation in RRA is required.
	Decision: Deferred evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
306.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	HISARTAN 80mg Tablet
	Composition	Each film coated tablet contains; Valsartan……80mg
	Diary No. Date of R & I & fee	Dy. No. 17040 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849819 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain

		ATC Code: C09CA03
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	VALSARTAN 80 MG FILM-COATED TABLETS 80 MG FILM-COATED TABLET - PL 08553/0700 MHRA Approved.
	Me-too status	Valbar 80mg Tablet Reg. No. 086702 M/s Barrett Hodgson Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved with USP specifications. 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 07-05-2021, before issuance of registration letter.	
307.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	AMVAL Plus 10mg Tablet
	Composition	Each film coated tablet contains; Amlodipine (as besylate)…..5mg Valsartan …….160mg
	Diary No. Date of R & I & fee	Dy. No. 17040 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849819 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code: C09DB01
	Type of Form	Form-5
	Finished product Specification	**Hi MED Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan Kappler 5 mg/80 mg, 5 mg/160 mg and 10 mg/160 mg film-coated tablets - PL 22363/0023-0025; UK/H/6785/001-003/DC MHRA Approved.
	Me-too status	Extor 5mg+160mg Reg. No. 054502 M/s Searle company Ltd. Lahore.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved with USP specifications. 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 07-05-2021, before issuance of registration letter.	
308.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section

	Brand Name + Dosage Form + Strength	AMPRIDE 50mg Tablet
	Composition	Each film coated tablet contains; Amisulpride……50mg
	Diary No. Date of R & I & fee	Dy. No. 17021 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786686 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	ANTIPSYCHOTICS, Benzamides ATC Code: N05AL05
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Amisulpride 50mg Tablets - PL 04416/0592 MHRA Approved.
	Me-too status	Amis 50mg Tablet Reg. No. 064017 M/s Genome Pharma Haripur
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required along with fee of Rs. 7500/-
	Decision: Approved with BP specifications and following label; **Each tablet contains;** **Amisulpride……50mg** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications and description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
309.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	GLIMED 2mg Tablet
	Composition	Each film coated tablet contains; Glimepiride……2mg
	Diary No. Date of R & I & fee	Dy. No. 17033 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786690 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Glimepiride 2 mg Tablets MHRA Approved.
	Me-too status	Amaryl tab 2 mg Reg. No. 019568 M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23, Sector 22 Korangi Industrial Area Karachi.

	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required along with fee of Rs. 7500/-
	Decision: Approved with USP specifications and following label; **Each tablet contains;** **Glimepiride……2mg** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications and description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
310.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MEFLOQUEN 250mg Tablet
	Composition	Each film coated tablet contains; Mefloquine ….250mg
	Diary No. Date of R & I & fee	Dy. No. 17024 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786691 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Methanolquinolines ATC Code: P01BC02
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MEFLOQUINE 250 MG TABLETS, LARIAM 250MG TABLETS MHRA Approved.
	Me-too status	Malarium 250mg Tablets Reg. No. 066319 M/s Global Pharma Islamabad
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required • The innovator uses HCl salt, whereas applied label is of base only. Correction along with full fee i.e. Rs. 30,000/- is required.
	Decision: Approved with USP specifications and following label; **Each tablet contains;** **Mefloquine as hydrochloride….250mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
311.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)

		Tablet (general) Section
	Brand Name + Dosage Form + Strength	MITRA 30mg Tablet
	Composition	Each film coated tablet contains; Mirtazapine…….30mg
	Diary No. Date of R & I & fee	Dy. No. 17022 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0810944 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antidepressants ATC code: N06AX11
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Mirtazapine 15 mg, 30 mg and 45 mg film-coated tablets - PL 28444/0097-9 MHRA Approved.
	Me-too status	Tazemir 15mg Tablet Reg. No. 058172 M/s Lisko Pakistan Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved with USP specifications. 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 07-05-2021, before issuance of registration letter.	
312.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	ONDAMED 8mg Tablet
	Composition	Each film coated tablet contains; Ondansetron as hydrochloride dehydrate…..4mg
	Diary No. Date of R & I & fee	Dy. No. 17041 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786696 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists. ATC Code: A04AA01
	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	Ondansetron 4 mg & 8 mg (Ondansetron Hydrochloride dihydrate) MHRA Approved.
	Me-too status	Zofran Tablets 4 mg Reg. No. 020667 M/s GSK Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Covering letter and fee is submitted for 8mg strength. Form-5 is submitted for 4mg strength. Correction along with full fee is required.

	Decision: Deferred for submission of Form-5 and complete details of 8mg strength.	
313.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	OLANODON 10mg Tablet
	Composition	Each film coated tablet contains; Olanzapine…..10mg
	Diary No. Date of R & I & fee	Dy. No. 17039 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786689 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Olanzapine 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg Tablets - PL 32854/0015-20 (Zyprexa coated) MHRA Approved.
	Me-too status	Olanzia Tablets 10mg Reg. no. 054721 M/s Werrick Pharma Islamabad.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved with USP specifications. 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 07-05-2021, before issuance of registration letter.	
314.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
	Brand Name + Dosage Form + Strength	ACIMED 10mg Capsule
	Composition	Each Capsule contains; Acitretin……10mg
	Diary No. Date of R & I & fee	Dy. No. 17031 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786688 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Retinoids for treatment of psoriasis ATC Code: D05BB02
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Acitretin 10 mg and 25 mg Capsules - PL 20117/0265-6 MHRA Approved.
	Me-too status	ACT 10mg Capsule Reg. No. 081575 M/s Ciba Pharmaceuticals Jamshoro
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.

	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved with USP specifications. 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 07-05-2021, before issuance of registration letter.	
315.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
	Brand Name + Dosage Form + Strength	MEBMED 200mg Capsule
	Composition	Each Capsule contains; Mebeverine hydrochloride (SR pellets 50%) 200mg Source: Vision Pharma
	Diary No. Date of R & I & fee	Dy. No. 17026 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786700 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group ATC Code: A03AA04
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specification's**
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Mebeverine 200 mg modified release capsules (mebeverine hydrochloride) - PL 35533/0095 MHRA Approved.
	Me-too status	Mebever MR 200mg Capsule Reg. No. 050747 M/s Getz Pharma Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
316.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
	Brand Name + Dosage Form + Strength	HImed 120mg Capsule
	Composition	Each Capsule contains; Orlistat (uncoated pellets 50%)……120mg Source: M/s Vision Pharmaceuticals.
	Diary No. Date of R & I & fee	Dy. No. 17027 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0832248 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Peripherally acting antiobesity products ATC Code: A08AB01
	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	Orlistat 120 mg hard capsules (orlistat) - PL 20416/0270 MHRA Approved.
	Me-too status	OSKER 120mg Capsules Reg. No. 066788 M/s Genix Pharma Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• The label claim on Form-5 is incorrect. Revised Form-5 along with full fee is required. • Real time and accelerated stability study data of 3 batches of pellets is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with fee of Rs. 30,000/- as per SRO496(I)/2023 dated 17.04.2023.** • **Real time and accelerated stability data of 3 batches of pellets.**	
317.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	EPAX-M 5mg+1000mg Tablet
	Composition	Each film coated tablet contains; Empagliflozin……5mg Metformin hydrochloride USP…..1000mg
	Diary No. Date of R & I & fee	Dy. No. 15009 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0826709 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	SYNJARDY 5 MG/1000 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Diampa-M Tablet 5mg+1000mg Reg. No. 103094 M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision:	
318.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	EPAX-M 5mg+500mg Tablet
	Composition	Each film coated tablet contains; Empagliflozin……5mg Metformin hydrochloride USP…..500mg
	Diary No. Date of R & I & fee	Dy. No. 15013 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0826712 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20

	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Synjardy Empagliflozin; Metformin HCl 5mg;500mg Tablet USFDA Approved.
	Me-too status	Diampa-M Tablet 5mg+500mg Reg. No. 105287 M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
319.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	EPAX-M 12.5mg+850mg Tablet
	Composition	Each film coated tablet contains; Empagliflozin……12.5mg Metformin hydrochloride USP…..850mg
	Diary No. Date of R & I & fee	Dy. No. 15011 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0742696 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	SYNJARDY 12.5 MG/850 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Diampa-M Tablet 12.5mg+850mg Reg. No. 105552 M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
320.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	EPAX-M 5mg+850mg Tablet
	Composition	Each film coated tablet contains; Empagliflozin……5mg Metformin hydrochloride USP…..850mg
	Diary No. Date of R & I & fee	Dy. No. 15011 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0742696 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20

	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	SYNJARDY 5 MG/850 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Diampa-M Tablet 5mg+850mg Reg. No. 103093 M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability study data as per the data requirements approved in 293rd meeting of Registration Board.	
321.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	EPAX-M 12.5mg+500mg Tablet
	Composition	Each film coated tablet contains; Empagliflozin……12.5mg Metformin hydrochloride USP…..500mg
	Diary No. Date of R & I & fee	Dy. No. 15012 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0742695 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Synjardy Empagliflozin; Metformin HCl 12.5mg;500mg Tablet USFDA Approved.
	Me-too status	Diampa-M Tablet 12.5mg+500mg Reg. No. 105551 M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability study data as per the data requirements approved in 293rd meeting of Registration Board.	
322.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	DPAX-M 5mg+850mg Tablet
	Composition	Each film coated tablet contains; Dapagliflozin propanediol monohydrate eq. to Dapagliflozin ……5mg Metformin hydrochloride USP…..850mg
	Diary No. Date of R & I & fee	Dy. No. 15015 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0742700 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15

	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Xigduo 5 mg/850 mg film-coated tablets MHRA Approved.
	Me-too status	DAPA-Met 5mg/850mg Reg. no. 093071 M/s Hilton Pharma Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
323.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	DPAX-M 5mg+1000mg Tablet
	Composition	Each film coated tablet contains; Dapagliflozin propanediol monohydrate eq. to Dapagliflozin ……5mg Metformin hydrochloride USP…..1000mg
	Diary No. Date of R & I & fee	Dy. No. 15014 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0826710 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Xigduo 5 mg/1000 mg film-coated tablets MHRA Approved.
	Me-too status	DAPA-Met 5mg/1000mg Reg. no. 093072 M/s Hilton Pharma Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
324.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	LERAM 250mg Tablet
	Composition	Each film coated tablet contains; Levetiracetam…….250mg
	Diary No. Date of R & I & fee	Dy. No. 15020 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0826713 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14
	Type of Form	Form-5
	Finished product Specification	USP specifications

	Pack size & Demanded Price	1x10's, 3x10's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LEVETIRACETAM RIVOPHARM 250 MG FILM-COATED TABLETS - PL 33155/0025 MHRA Approved.
	Me-too status	Vicet Tablet 250mg Re. No. 061773 M/s Martin Dow Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision: Approved.	
325.	Name and address of manufacturer/ Applicant	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road, Layyah. (DML No. 000774) Tablet (general) Section
	Brand Name + Dosage Form + Strength	LERAM 500mg Tablet
	Composition	Each film coated tablet contains; Levetiracetam…….500mg
	Diary No. Date of R & I & fee	Dy. No. 15019 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0742699 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1x10's, 3x10's, 10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LEVETIRACETAM RIVOPHARM 500 MG FILM-COATED TABLETS - PL 33155/0026 MHRA Approved.
	Me-too status	Vicet Tablet 500mg Re. No. 061774 M/s Martin Dow Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
	Decision: Approved.	
326.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-KM, Ferozupur Road, Lahore. (DML No. 000389) Tablet (general) Section
	Brand Name + Dosage Form + Strength	FERPRIDE 50mg Tablet
	Composition	Each tablet contains; Levosulpiride……50mg
	Diary No. Date of R & I & fee	Dy. No. 17339 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839957 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	ANTIPSYCHOTICS, Benzamides, ATC Code:N05AL07
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	LEVOPRAID® 50 mg Tablets by TEOFARMA Srl. Approved by AIFA Italy
	Me-too status	Sapride Tablet 50mg Reg. No. 049950

		M/s Standpharm Pakistan Lahore.
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report.	
327.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-KM, Ferozupur Road, Lahore. (DML No. 000389) Tablet (general) Section
	Brand Name + Dosage Form + Strength	RELAXFER 2mg Tablet
	Composition	Each tablet contains; Tizanidine (HCl)….2mg
	Diary No. Date of R & I & fee	Dy. No. 17343 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0797035 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other centrally acting agents ATC Code: M03BX02
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	TIZANIDINE 2MG TABLETS MHRA Appoved.
	Me-too status	Zodin 2mg Tablet Reg. No. 063400 M/s Bio-Labs Islamabad.
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Monograph of applied product is available in pharmacopoeia, applied specs are Innovator. Clarification or correction along with requisite fee is required.
	Decision: Approved with USP Specifications. **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
328.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-KM, Ferozupur Road, Lahore. (DML No. 000389) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Lizo 600mg Tablet
	Composition	Each tablet contains; Linezolid …..600mg
	Diary No. Date of R & I & fee	Dy. No. 17340 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839964 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antibacterials ATC Code: J01XX08
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Linezolid 600mg Film-Coated Tablets (linezolid) - PL 20416/0517

		MHRA approved.
	Me-too status	Linzy Tablets 600mg Reg. no. 063415 M/s Global Pharma Islamabad.
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • The product approved in RRA is film coated, applied product is uncoated. Correction along with requisite fee is required.
	Decision: Approved with following label; **"Each film coated tablet contains;** **Linezolid …. 600mg"** **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
329.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-KM, Ferozupur Road, Lahore. (DML No. 000389) Tablet (general) Section
	Brand Name + Dosage Form + Strength	FEROXIB 60mg Tablet
	Composition	Each tablet contains; Etoricoxib……60mg
	Diary No. Date of R & I & fee	Dy. No. 17338 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839959 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Coxibs ATC Code: M01AH05
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Etoricoxib 30 mg, 60 mg, 90 mg and 120 mg film-coated tablets - PL 20416/0543-0546 MHRA approved.
	Me-too status	Etoria 60mg Tablet Reg. No. 080818 M/s Hygeia Pharmaceuticals Islamabad.
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
330.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-KM, Ferozupur Road, Lahore. (DML No. 000389) Tablet (general) Section
	Brand Name + Dosage Form + Strength	ITP-FER 50mg Tablet
	Composition	Each tablet contains; Itopride (HCl)……50mg
	Diary No. Date of R & I & fee	Dy. No. 17344 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0797031 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Propulsives ATC Code: A03FA07
	Type of Form	Form-5

	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Itopride hydrochloride tablet 50 mg by Shiseido Pharmaceutical Co., Ltd. PMDA approved
	Me-too status	Ganaton 50mg Tablet by M/s Abbott. (Reg. # 028429)
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • RRA approved product uses Itopride HCl 50mg, in applied formulation 50mg base is mentioned. Further innovator product is coated applied is uncoated. Correction as per innovator product is required along with full fee.
	Decision: Approved with following label; **Each film coated tablet contains;** **Itopride HCl……50mg** **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
331.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-KM, Ferozupur Road, Lahore. (DML No. 000389) Tablet (general) Section
	Brand Name + Dosage Form + Strength	VILDAFER-MET 50mg/850mg Tablet
	Composition	Each tablet contains; Vildagliptin …….50mg Metformin HCl…..850mg
	Diary No. Date of R & I & fee	Dy. No. 17342 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0797028 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs. ATC Code: A10BD08
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Galvumet Film Coated Tablets (50 mg vildagliptin and 850 mg metformin hydrochloride) Swissmedic Approved
	Me-too status	Vilfor 50/850mg tablet Reg. No. 106507 M/s Hi-Medic Pharmaceuticals (Pvt) Ltd Lahore
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Innovator product is coated applied is uncoated. Correction as per innovator product is required along with requisite fee.
	Decision: Approved with following label; **"Each film coated tablet contains;** **Vildagliptin …….50mg** **Metformin HCl ….. 850mg"** **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
332.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-KM, Ferozupur Road, Lahore. (DML No. 000389)

		Tablet (general) Section
	Brand Name + Dosage Form + Strength	Lexolfer 2.5mg Tablet
	Composition	Each tablet contains; Letrozole…..2.5mg
	Diary No. Date of R & I & fee	Dy. No. 17341 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0797034 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Aromatase inhibitors ATC Code: L02BG04
	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	Letrozole 2.5 mg Film-coated tablets - PL 25258/0198 MHRA Approved.
	Me-too status	Femara 2.5mg Tablets Reg. No. 021129 M/s Novartis Pharma Karachi.
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Innovator product is coated applied is uncoated. Correction as per innovator product is required along with requisite fee.
	Decision: Approved with following label; **Each film coated tablet contains;** **Letrozole…..2.5mg** **Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
333.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	DROZOL-T Ophthalmic Solution
	Composition	Each 1ml contains; Dorzolamide HCL 22.26mg eq to Dorzolamide…..20mg Timolol maleate 6.85mg eq to Timolol…..…5mg
	Diary No. Date of R & I & fee	Dy. No. 14051 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0605449 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Beta blocking agents, timolol, combinations ATC Code: S01ED51
	Type of Form	Form-5
	Finished product Specification	**Manufacturer's Specifications (available in USP, JP & BP)**
	Pack size & Demanded Price	5mL. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Dorzolamide/Timolol 20 mg/ml + 5 mg/ml Eye Drops Solution - PL 00289/1130; UK/H/1505/001/DC MHRA Approved.
	Me-too status	Dorlol eye Drops Reg. No. 073468 M/s Genix Pharma Karachi.
	GMP status	Report of 2018 is submitted.

	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Specifications of finished product are mentioned as Manufacturer Specifications. Monograph is available in pharmacopoeia. Clarification or correction along with requisite fee is required.
	Decision: Approved with USP Specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
334.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Alrex-T Ophthalmic Suspension
	Composition	Each 1ml contains; Loteprednol Etabonate…..5mg Tobramycin……..3mg
	Diary No. Date of R & I & fee	Dy. No. 14060 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0549396 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antibiotics ATC Code: S01AA12 ANTIINFLAMMATORY AGENTS ATC Code: S01BA14
	Type of Form	Form-5
	Finished product Specification	**USP Specifications. (not in pharmacopoeia)**
	Pack size & Demanded Price	5mL. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Zylet 0.5%/0.3% ophthalmic Suspension USFDA Approved.
	Me-too status	Lotepred-T Ophtalmic Suspension Reg. No. 070515 M/s Sante (Pvt.) ltd. Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Specifications of finished product are mentioned as USP specs. Monograph for reference is required.
	Decision: Approved with innovator's specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
335.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Careprost Ophthalmic Solution
	Composition	Each 1ml contains; Bimatoprost…….0.3mg
	Diary No. Date of R & I & fee	Dy. No. 14055 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0549393 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Prostaglandin analogues ATC Code: S01EE03
	Type of Form	Form-5

	Finished product Specification	**Manufacturers Specifications**
	Pack size & Demanded Price	3ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	BIMATOPROST NEON HEALTHCARE 0.3 MG/ML EYE DROPS, SOLUTION - PL 45043/0010 MHRA Approved.
	Me-too status	Lureye Ophtalmic Solution 0.03% Reg. No. 083011 M/s Atco laboratories Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with innovator's specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
336.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Nevan Ophtalmic Suspension
	Composition	Each ml contains; Nepafenac ……1mg
	Diary No. Date of R & I & fee	Dy. No. 14047 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0605444 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antiinflammatory agents, non-steroids ATC Code: S01BC10
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specifications**
	Pack size & Demanded Price	5ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities	NEVANAC 1 MG/ML EYE DROPS SUSPENSION MHRA Approved.
	Me-too status	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with innovator's specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
337.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Optidex-T Ophthalmic Suspension
	Composition	Each 1ml contains; Dexamethasone……..1mg Tobramycin……3mg
	Diary No. Date of R & I & fee	Dy. No. 14052 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0605448 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	dexamethasone and antiinfectives ATC Code: S01CA01

	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	TOBRAMYCIN + DEXAMETHASONE (3 MG/ML + 1 MG/ML) EYE DROPS, SUSPENSION - PL 31103/0010 MHRA Approved.
	Me-too status	Tobradex Suspension Reg. No. 017040 M/s Novartis Pharma Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report.	
338.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Fluoro-T ophthalmic suspension
	Composition	Each 1ml contains; Fluorometholone……...1mg Tetrahydrozoline HCl…..0.25mg
	Diary No. Date of R & I & fee	Dy. No. 14054 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0549392 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Sympathomimetics used as decongestants ATC Code: S01GA52
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specifications**
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified
	Me-too status	Femicon Ophthalmic suspension 5ml Reg. No. 012112 M/s Remington Pharmaceutical Industries Lahore.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **submission of valid GMP certificate or latest GMP inspection report.**	
339.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	BIOPAT DS Ophthalmic solution (5ml)
	Composition	Each ml contains Olopatadine HCl 2.22mg eq. to Olopatadine …..2mg
	Diary No. Date of R & I & fee	Dy. No. 14056 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0605447 dated 05-03-2019, endorsed on

		06.03.2019.
	Pharmacological Group	Other antiallergics ATC Code: S01GX09
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Olopatadine hydrochloride eq 0.2% base Solution Ophthalmic USFDA Approved.
	Me-too status	Optidine eye drops 0.2% Reg. No. 092845 M/s Hudson Pharma Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report.	
340.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Biopat Ophthalmic solution
	Composition	Each ml contains Olopatadine HCl 1.11mg eq. to Olopatadine …..1mg
	Diary No. Date of R & I & fee	Dy. No. 14049 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0605446 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiallergics ATC Code: S01GX09
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Olopatadine 1mg/ml eye drops, solution - (olopatadine hydrochloride) - PL 04569/1366; UK/H/4541/001/DC MHRA Approved.
	Me-too status	Winolap 0.1% Ophthalmic solution Reg. No. 067397 M/s ATCO Laboratories Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report.	
341.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Systears Lubricant eye drops
	Composition	Each ml contains; Polyethylene glycol ..….4mg Propylene glycol……...3mg
	Diary No. Date of R & I & fee	Dy. No. 14048 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0605445 dated 05-03-2019, endorsed on 06.03.2019.

	Pharmacological Group	Eye lubricant.
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specifications (not in pharmacopoeia)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	EyeLub Reg. No. 063198 M/s Shaigan Rawalpindi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **submission of valid GMP certificate or latest GMP inspection report.**	
342.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	UNILAT Ophthalmic Solution
	Composition	Each ml contains; Latanoprost……50mcg
	Diary No. Date of R & I & fee	Dy. No. 14058 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0549397 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Prostaglandin analogues ATC Code: S01EE01
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specifications (not in pharmacopoeia)**
	Pack size & Demanded Price	2.5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LATOP 50 MICROGRAMS/ML EYE DROPS SOLUTION MHRA Approved.
	Me-too status	Prostile eye Drops Reg. no. 029948 M/s Remington Pharma Lahore.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with innovator's specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
343.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	CO-LATAN Ophthalmic Solution
	Composition	Each ml contains; Latanoprost……50mcg

		Timolol maleate 6.85mg eq to timolol …..5mg
	Diary No. Date of R & I & fee	Dy. No. 14059 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0710229 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Ophthalmological-betablocking agents - timolol, combinations ATC code: S01ED51
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specifications (not in pharmacopoeia)**
	Pack size & Demanded Price	2.5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Latanoprost+Timolol 50 micrograms/ml 5 mg/ml eye drops solution - PL 18956/0020 MHRA Approved.
	Me-too status	Xalacom Eye Drops Reg. No. 031386 M/s Pfizer Pakistan Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with innovator's specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
344.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Levoxin Ophthalmic Solution
	Composition	Each ml contains; Levofloxacin hemihydrate eq to levofloxacin….15mg
	Diary No. Date of R & I & fee	Dy. No. 14053 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0555543 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: S01AE05
	Type of Form	Form-5
	Finished product Specification	**USP Specifications (couldn't be found in USP, available in JP)**
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LEVOFLOXACIN 5MG/ML EYE DROPS SOLUTION MHRA Approved.
	Me-too status	Qumic eye drops Reg. No. 042185 M/s Bosch Pharma Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with JP specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
345.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586)

		Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	FOLON Ophthalmic Solution
	Composition	Each ml contains; Ofloxacin……3mg
	Diary No. Date of R & I & fee	Dy. No. 14057 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0549395 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: S01AE01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	EXOCIN 3 MG/ML EYE DROPS SOLUTION. MHRA Approved.
	Me-too status	Oflocin Eye rops 0.3% Reg. No. 030594 M/s Helix Pharma Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report.	
346.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	TOBRIN Ophthalmic Solution
	Composition	Each ml contains; Tobramycin……3mg
	Diary No. Date of R & I & fee	Dy. No. 14056 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0549394 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antibiotics ATC Code: S01AA12
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Tobramycin 0.3% Solution drops Ophthalmic USFDA Approved.
	Me-too status	TOBREX Eye Drops Reg. No. 097352 M/s Novartis Pharma Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report.	
347.	Name and address of manufacturer/ Applicant	M/s. Webros Pharmaceuticls, Plot No. 1, Street 10, National Industrial Zone, Rawat (contract giver) (DML No.000538) Contract with M/s. Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar (Contract Acceptor) (DML No.000374)

		Injectable Vial Cephalosporin Section.
	Brand Name + Dosage Form + Strength	CEFOP Injection 2gm
	Composition	Each vial contains; Cefoperazone Sodium equivalent to Cefoperzone…1g Sulbactam Sodium equivalent to Sulbactam.....…1g
	Diary No. Date of R & I & fee	Dy. No. 16820 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0817482 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01DD62 cefoperazone and beta-lactamase inhibitor
	Type of Form	Form-5
	Finished product Specification	Not mentioned (Available in JP)
	Pack size & Demanded Price	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	Q-Bact 2gm Injection Reg. No. 061170 M/s High-Q International Karachi.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Reference of finished product specifications is reuired.
	Decision: Approved with JP specifications. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report of M/s bloom, fee of Rs. 7,500/- as per SRO 496(I)/2023 dated 17.04.2023 and report of satisfactory capacity assessment of manufacturing & testing facility of M/s Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar.	
348.	Name and address of manufacturer/ Applicant	M/s. Webros Pharmaceuticls, Plot No. 1, Street 10, National Industrial Zone, Rawat (contract giver) (DML No.000538) Contract with M/s. Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar (Contract Acceptor) (DML No.000374) Injectable Vial Cephalosporin Section.
	Brand Name + Dosage Form + Strength	CEFOP Injection 1gm
	Composition	Each vial contains; Cefoperazone Sodium equivalent to Cefoperzone…500mg Sulbactam Sodium equivalent to Sulbactam.....…500mg
	Diary No. Date of R & I & fee	Dy. No. 16821 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0817481 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01DD62 cefoperazone and beta-lactamase inhibitor
	Type of Form	Form-5
	Finished product Specification	Not mentioned (Available in JP)
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	SULPERAZONE FOR INTRAVENOUS INJECTION 1G PDMA JAPAN APPROVED.
	Me-too status	Q-Bact 1gm Injection Reg. No. 061169 M/s High-Q International Karachi.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Reference of finished product specifications is reuired.

	Decision: Approved with JP specifications. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report of M/s bloom, fee of Rs. 7,500/- as per SRO 496(I)/2023 dated 17.04.2023 and report of satisfactory capacity assessment of manufacturing & testing facility of M/s Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar.	
349.	Name and address of manufacturer/ Applicant	M/s. Webros Pharmaceuticls, Plot No. 1, Street 10, National Industrial Zone, Rawat (contract giver) (DML No.000538) Contract with M/s. Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar (Contract Acceptor) (DML No.000374) Injectable Vial Cephalosporin Section.
	Brand Name + Dosage Form + Strength	COV Injection 500mg
	Composition	Each vial contains; Cefepime as HCL with L-arginine eq to Cefepime..…500mg
	Diary No. Date of R & I & fee	Dy. No. 16823 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0817479 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01DE01 Fourth-generation cephalosporins
	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	Cefepime hydrochloride eq to 500mg base/ vial. USFDA Approved.
	Me-too status	Avepime Injection 500mg Reg. No. 059586 M/s Aventek Pharmaceuticals Lahore.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with JP specifications. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report of M/s bloom and report of satisfactory capacity assessment of manufacturing & testing facility of M/s Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar..	
350.	Name and address of manufacturer/ Applicant	M/s. Webros Pharmaceuticls, Plot No. 1, Street 10, National Industrial Zone, Rawat (contract giver) (DML No.000538) Contract with M/s. Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar (Contract Acceptor) (DML No.000374) Injectable Vial Cephalosporin Section.
	Brand Name + Dosage Form + Strength	COV Injection 1gm
	Composition	Each vial contains; Cefepime as HCL with L-arginine eq to Cefepime..…1g
	Diary No. Date of R & I & fee	Dy. No. 16822 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0817480 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01DE01 Fourth-generation cephalosporins
	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	Cefepime hydrochloride eq to 1000mg base/ vial. USFDA Approved.
	Me-too status	Avepime Injection 1gm Reg. No. 059585 M/s Aventek Pharmaceuticals Lahore.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with JP specifications. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report of M/s Bloom, fee of Rs. 7,500/- as per SRO 496(I)/2023 dated 17.04.2023 and report of satisfactory capacity assessment of manufacturing & testing facility of M/s Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar.	
351.	Name and address of manufacturer/ Applicant	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Raod, Lahore (DML No. 000563). Section
	Brand Name + Dosage Form + Strength	PAINCARE 5% W/W gel
	Composition	Each 100gram contains; Ibuprofen BP……5%W/W
	Diary No. Date of R & I & fee	Dy. No. 16434 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0812231 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Propionic acid derivatives ATC Code: M01AE01
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	25gm, 30gm. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only - PL 00063/0706-0707 MHRA Approved.
	Me-too status	Could not be verified.
	GMP status	Not submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section approval is required. • Reference of finished product specifications is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required.
	Decision: Deferred for following; • **Latest GMP inspection report/ certificate.** • **Evidence of section approval.** • **Submission of application on Form-5D along with stability study data as per the guidelines approved in 293rd meeting of Registration Board.**	
352.	Name and address of manufacturer/ Applicant	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road, Lahore (DML No. 000563). Section
	Brand Name + Dosage Form + Strength	NEPCARE 0.1% Ophthalmic Suspension
	Composition	Each ml of suspension contains;

		Nepafenac ……1mg
	Diary No. Date of R & I & fee	Dy. No. 16433 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0812229 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Antiinflammatory agents, non-steroids ATC Code: S01BC10
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	NEVANAC 1 MG/ML EYE DROPS SUSPENSION MHRA Approved.
	Me-too status	Nepanac Ophthalmic Suspension Reg. No. 069177 M/s Remington Pharma Lahore.
	GMP status	Not submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Reference of finished product specifications is required.
	Decision: Approved with innovator's specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
353.	Name and address of manufacturer/ Applicant	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road, Lahore (DML No. 000563). Section
	Brand Name + Dosage Form + Strength	GRAVICARE 12.5mg/5ml Syrup
	Composition	Each 5ml contains; Dimenhydrinate USP…..12.5mg
	Diary No. Date of R & I & fee	Dy. No. 16430 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0812232 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Aminoalkyl ethers ATC Code: R06AA11
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	60ml, 90ml, 120ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed for per 5ml
	GMP status	Not submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Reference of finished product specifications is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith 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 is required.
	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.** • **Latest GMP inspection report/ certificate.**	
354.	Name and address of manufacturer/ Applicant	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road, Lahore (DML No. 000563). Section
	Brand Name + Dosage Form + Strength	CAREPROFEN GEL 2.5% Gel
	Composition	Each gram contains; Ketoprofen BP……..25mg
	Diary No. Date of R & I & fee	Dy. No. 16429 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0812233 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antiinflammatory preparations, non-steroids for topical use ATC Code: M02AA10
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	25gm, 30gm. As per SRO.
	Approval status of product in Reference Regulatory Authorities	KETOPROFEN 2.5% W/W GEL MHRA Apprved.
	Me-too status	Fastum Topical Gel 2.5% Reg. No. 099502 M/s Pharmatec Pakistan Karachi.
	GMP status	Not submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Reference of finished product specifications is required.
	Decision: Approved with innovator's specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
355.	Name and address of manufacturer/ Applicant	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road, Lahore (DML No. 000563). Section
	Brand Name + Dosage Form + Strength	PIROCARE 0.5% Gel
	Composition	Each gram contains; Piroxicam……..5mg
	Diary No. Date of R & I & fee	Dy. No. 16431 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0812234 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antiinflammatory preparations, non-steroids for topical use ATC Code: M02AA07
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	25gm. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Piroxicam Manx 0.5% w/w gel - PL 14251/0028 MHRA Approved.
	Me-too status	Feldene Gel 0.5% Reg. No. 012817 M/s Pfizer Pakistan Karachi

	GMP status	Not submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Reference of finished product specifications is required.
	Decision: Approved with innovator's specifications. **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
356.	Name and address of manufacturer/ Applicant	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road, Lahore (DML No. 000563). Section
	Brand Name + Dosage Form + Strength	ALBENDACARE 200mg/5ml Suspension
	Composition	Each 5ml contains; Albendazole USP……..200mg
	Diary No. Date of R & I & fee	Dy. No. 16432 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0812231 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Benzimidazole derivatives ATC Code: P02CA03
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	10ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Benza 200 suspension 200mg/5ml Reg. No. 059857 M/s Searle Company Lahore.
	GMP status	Not submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Reference of finished product specifications is required.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **Latest GMP inspection report/ certificate.**	
357.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	Ceftranor 500mg IV Injection
	Composition	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone (USP)…..500mg
	Diary No. Date of R & I & fee	Dy. No. 16047 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 08118830 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins.

		ATC Code: J01DD04
	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	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Pwder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Zetox 500mg Injection Reg. No. 053145 M/s Lahore Pharma.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi.	
358.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	Ceftranor 1g IV Injection
	Composition	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone (USP)…..1g
	Diary No. Date of R & I & fee	Dy. No. 16048 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0811829 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	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	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Powder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Rocephin IV/IM Injection 1gm Reg. No. 007014 M/s Martin Dow Karachi
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi.	
359.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) (contract giver).

		Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	Ceftranor 2g IV Injection
	Composition	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone (USP)…..2g
	Diary No. Date of R & I & fee	Dy. No. 16054 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0844385 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	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	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Powder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Traxon 2gm IM/IV Injection Reg. No. 018248 (Import) M/s Akhai Agencies Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi.	
360.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	NORCEFF 1gm injection
	Composition	Each vial contains; Cefoperazone sodium…….500mg Sulbactam sodium……..500mg
	Diary No. Date of R & I & fee	Dy. No. 16052 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0844383 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor. ATC Code: J01DD62
	Type of Form	Form-5
	Finished product Specification	Not mentioned

	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	SULPERAZONE FOR INTRAVENOUS INJECTION 1G PDMA JAPAN APPROVED.
	Me-too status	Q-Bact 1gm Injection Reg. No. 061169 M/s High-Q International Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	i. The salt/hydrate of API is mentioned as is in label. Revision of label claim is required as per innovator product along with submission of full fee i.e. Rs. 75000/- ii. Reference of product specifications is required.
	Decision: Approved with JP specifications and following label claim; **Each vial contains;** **Cefoperazone as sodium…….500mg** **Sulbactam as sodium……..500mg** **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi and submission of fee of Rs. 7,5000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
361.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	NORCEFF 1gm injection
	Composition	Each vial contains; Cefoperazone sodium…….1000mg Sulbactam sodium……..1000mg
	Diary No. Date of R & I & fee	Dy. No. 16053 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0844384 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor. ATC Code: J01DD62
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	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	Q-Bact 2gm Injection Reg. No. 061170 M/s High-Q International Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	i. The salt/hydrate of API is mentioned as is in label. Revision of label claim is required as per innovator product along with submission of full fee i.e. Rs. 75000/-

		ii. Reference of product specifications is required.
	Decision: Approved with JP specifications and following label claim; **Each vial contains;** **Cefoperazone as sodium…….1000mg** **Sulbactam as sodium……..1000mg** **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi and submission of fee of Rs. 7,5000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
362.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Capsule (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	NORXIME 400mg Capsule
	Composition	Each Capsule Contains; Cefixime as Cefixime trihydrate……..400mg
	Diary No. Date of R & I & fee	Dy. No. 16050 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0811826 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	SUPRAX (CEFIXIME) CAPSULES 400MG USFDA APPROVED.
	Me-too status	Cefspan 400mg Capsules Reg. No. 013860 M/s Barret Hodgson Pakistan Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi.	
363.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Suspension (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	NORXIME 100mg/5ml Suspension

	Composition	Each 5ml Contains; Cefixime as Cefixime trihydrate…….100mg
	Diary No. Date of R & I & fee	Dy. No. 16051 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0811827 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cefixime 100 mg/5 mL Powder for Oral Suspension - PL 04569/1118; UK/H/2828/001/DC MHRA Approved.
	Me-too status	Fixicef Powder for oral suspension Reg. No. 080273 M/s Atco Laboratories Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi.	
364.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Suspension (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	NORXIME 200mg/5ml Suspension
	Composition	Each 5ml Contains; Cefixime as Cefixime trihydrate…….200mg
	Diary No. Date of R & I & fee	Dy. No. 16049 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0811825 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Suprax 200mg/5ml USFDA Approved.
	Me-too status	Cefspan D.S Suspension Reg. No. 024634 M/s Barret Hodgson Pakistan Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	• Reference of finished product specifications is required.
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing	

	and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi.	
365.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals 494, Sunder Industrial Estate, Raiwind Road, Lahore (DML No. 000818). Capsule (general) Section
	Brand Name + Dosage Form + Strength	GABIPRO 50mg Capsule
	Composition	Each Capsule Contains; Pregabalin……50mg
	Diary No. Date of R & I & fee	Dy. No. 16900 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0806292 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of Form	Form-5
	Finished product Specification	**Not mentioned.**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	PREGABALIN MSN 50 MG HARD CAPSULES - PL 50805/0037 MHRA Approved.
	Me-too status	Gabica 50mg Cap Reg. No. 048725 M/s Getz Pharma Karachi
	GMP status	Certificate issued on basis of inspection of 2017 is submitted.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Latest GMP certificate/inspection report is required.
	Decision: Approved with BP Specifications. 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 07-05-2021, before issuance of registration letter.	
366.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals 494, Sunder Industrial Estate, Raiwind Road, Lahore (DML No. 000818). Tablet (general) Section
	Brand Name + Dosage Form + Strength	Zesyl 2mg Tablet
	Composition	Each Tablet Contains; Perindopril (as terbutylamine)…..2mg
	Diary No. Date of R & I & fee	Dy. No. 15997 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0806283 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	ACE inhibitors, plain ATC Code: C09AA04
	Type of Form	Form-5
	Finished product Specification	**Not mentioned.**
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PERINDOPRIL ERBUMINE 2 MG FILM-COATED TABLETS - PL 49565/0046 MHRA Approved.
	Me-too status	Peripril 2mg Tablet Reg. No. 037057 M/s Macter International Karachi.
	GMP status	Certificate issued on basis of inspection of 2017 is submitted.

	Remarks of the Evaluator	• Reference of finished product specifications is required. • Latest GMP certificate/inspection report is required. • Product approved in RRA is film coated. Applied product is uncoated. Correction along with fee of Rs. 7500/- is required.
	Decision: Approved with USP specifications with following label; **Each Film Coated Tablet Contains;** **Perindopril (as terbutylamine)…..2mg** **Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
367.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals 494, Sunder Industrial Estate, Raiwind Road, Lahore (DML No. 000818). Tablet (general) Section
	Brand Name + Dosage Form + Strength	Zesyl 4mg Tablet
	Composition	Each Tablet Contains; Perindopril (as terbutylamine)…..4mg
	Diary No. Date of R & I & fee	Dy. No. 15998 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0806284 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	ACE inhibitors, plain ATC Code: C09AA04
	Type of Form	Form-5
	Finished product Specification	**Not mentioned.**
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PERINDOPRIL ERBUMINE 4 MG FILM-COATED TABLETS - PL 21880/0216 MHRA Approved.
	Me-too status	Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.
	GMP status	Certificate issued on basis of inspection of 2017 is submitted.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Latest GMP certificate/inspection report is required. • Product approved in RRA is film coated. Applied product is uncoated. Correction along with fee of Rs. 7500/- is required.
	Decision: Approved with USP specifications with following label; **Each Film Coated Tablet Contains;** **Perindopril (as terbutylamine)…..4mg** **Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
368.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals 494, Sunder Industrial Estate, Raiwind Road, Lahore (DML No. 000818). Tablet (general) Section
	Brand Name + Dosage Form + Strength	Zesyl 8mg Tablet
	Composition	Each Tablet Contains;

		Perindopril (as terbutylamine)…..8mg
	Diary No. Date of R & I & fee	Dy. No. 15999 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0806285 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	ACE inhibitors, plain ATC Code: C09AA04
	Type of Form	Form-5
	Finished product Specification	**Not mentioned.**
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PERINDOPRIL ERBUMINE 8 MG FILM-COATED TABLETS - PL 21880/0217 MHRA Approved.
	Me-too status	Hartace Tablets 8mg Reg. No. 064429 M/s CSH Pharma Peshawar.
	GMP status	Certificate issued on basis of inspection of 2017 is submitted.
	Remarks of the Evaluator	• Reference of finished product specifications is required. • Latest GMP certificate/inspection report is required. • Product approved in RRA is film coated. Applied product is uncoated. Correction along with fee of Rs. 7500/- is required.
	Decision: Approved with USP specifications with following label; **Each Film Coated Tablet Contains;** **Perindopril (as terbutylamine)…..8mg** **Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
369.	Name and address of manufacturer/ Applicant	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar. - (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	RAKAZONE 1gm injection
	Composition	Each vial contains; Cefoperazone sodium…….500mg Sulbactam sodium……..500mg
	Diary No. Date of R & I & fee	Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor. ATC Code: J01DD62
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	SULPERAZONE FOR INTRAVENOUS INJECTION 1G PDMA JAPAN APPROVED.

	Me-too status	Q-Bact 1gm Injection Reg. No. 061169 M/s High-Q International Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	i. The salt/hydrate of API is mentioned as is in label. Revision of label claim is required as per innovator product along with submission of full fee i.e. Rs. 75000/- ii. Reference of product specifications is required.
	Decision: Approved with JP specifications and following label claim; **Each vial contains;** **Cefoperazone as sodium…….500mg** **Sulbactam as sodium……..500mg** **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi and submission of fee of Rs. 7,5000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
370.	Name and address of manufacturer/ Applicant	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar. - (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	RAKAZONE 2gm injection
	Composition	Each vial contains; Cefoperazone sodium…….1000mg Sulbactam sodium……..1000mg
	Diary No. Date of R & I & fee	Dy. No. 16202 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0825762 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor. ATC Code: J01DD62
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	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	Q-Bact 2gm Injection Reg. No. 061170 M/s High-Q International Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	i. The salt/hydrate of API is mentioned as is in label. Revision of label claim is required as per innovator product along with submission of full fee i.e. Rs. 75000/- ii. Reference of product specifications is required.
	Decision: Approved with JP specifications and following label claim; **Each vial contains;** **Cefoperazone as sodium…….1000mg**	

	Sulbactam as sodium……..1000mg **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi and submission of fee of Rs. 7,5000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
371.	Name and address of manufacturer/ Applicant	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar. - (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder (General) Injection Section.
	Brand Name + Dosage Form + Strength	LOZAMEP 40mg Infusion (IV)
	Composition	Each vial Contains; Omeprazole…40mg
	Diary No. Date of R & I & fee	Dy.No. 16200 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0825760 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC01
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion (omeprazole sodium) - PL 10622/0232 MHRA APPROVED.
	Me-too status	Risek 40mg Infusion Reg. No. 024170 M/s Getz Pharma Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	i. The salt/hydrate of API is not considered in label. Revision of label claim is required as per innovator product along with submission of full fee i.e. Rs. 75000/- ii. Reference of product specifications is required.
	Decision: Approved with innovator's specifications and following label claim; **Each vial contains;** **Omeprazole Sodium equivalent to Omeprazole…….40mg** **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi and submission of fee of Rs. 7,5000/- for correction/pre-approval change in salt form of drug substance as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
372.	Name and address of manufacturer/ Applicant	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar. - (DML No. 000386) (contract giver). Contract with M/s Nortech Pharmaceuticals (pvt.) Ltd. 203, Industrial Triangle Kahuta Road Islamabad. (DML No.000792) contract acceptor Liquid Ampoule (General) Section.

	Brand Name + Dosage Form + Strength	RAKA Injection 5mg/ml
	Composition	Each 1ml Ampoule contains; Colecalciferol…….5mg
	Diary No. Date of R & I & fee	Dy. No. 16209 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0825773 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Vitamin D
	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	VITAMIN D3 BON 200,000 IU/1 ml solution for injection IM ampoule ANSM France Approved.
	Me-too status	Sunny D Insta Ampoule Reg. No. 063450 M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Nortech Pharmaceuticals (pvt.) Ltd. 203, Industrial Triangle Kahuta Road Islamabad and 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 07-05-2021, before issuance of registration letter.**	
373.	Name and address of manufacturer/ Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	HEPDISOL 550mg Tablet
	Composition	Each tablet contains; Rifaximin……550mg
	Diary No. Date of R & I & fee	Dy.No. 16438 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805858 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antibiotics ATC Code: A07AA11
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	TARGAXAN 550 MG FILM-COATED TABLETS MHRA AAPPROVED.
	Me-too status	Rifaxa 550mg Tablet Reg. No. 071661 M/s Ferozsons Laboratories Nowshera
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report is required. • Reference of finished product specifications is required. • Innovator product is film coated, applied is uncoated. Correction along with fee of Rs. 7500/- is required.

	Decision: Approved with innovator's specifications and following label; **Each film tablet contains;** **Rifaximin……550mg** **Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
374.	Name and address of manufacturer/ Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	HEPDISOL 200mg Tablet
	Composition	Each tablet contains; Rifaximin……200mg
	Diary No. Date of R & I & fee	Dy.No. 16437 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805857 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antibiotics ATC Code: A07AA11
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	XIFAXANTA 200 MG FILM-COATED TABLETS MHRA AAPPROVED.
	Me-too status	Zerifex 200mg Tablet Reg. No. 070709 M/s AGP (Pvt.) Ltd. Karachi.
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report is required. • Reference of finished product specifications is required. • Innovator product is film coated, applied is uncoated. Correction along with fee of Rs. 7500/- is required.
	Decision: Approved with innovator's specifications and following label; **Each film tablet contains;** **Rifaximin……200mg** **Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
375.	Name and address of manufacturer/ Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Capsule (Ceph) Section.
	Brand Name + Dosage Form + Strength	CEPOSAL 100mg Capsule
	Composition	Each capsule contains; Cefpodoxime (as proxetil)……100mg
	Diary No. Date of R & I & fee	Dy.No. 16434 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805854 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD13
	Type of Form	Form-5

	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Medidoxim Capsule 100mg Reg. no. 062564 M/s Medisave Pharmaceuticals Lahore.
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report is required. • Reference of finished product specifications is required. • Evidence of product approval in RRA is required.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **Latest GMP inspection report.** • **Reference of finished product specifications.**	
376.	Name and address of manufacturer/ Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Capsule (Ceph) Section.
	Brand Name + Dosage Form + Strength	CEPOSAL 200mg Capsule
	Composition	Each capsule contains; Cefpodoxime (as proxetil)……200mg
	Diary No. Date of R & I & fee	Dy.No. 16436 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805856 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD13
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	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	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report is required. • Reference of finished product specifications is required. • Evidence of me-too and product approval in RRA 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 inspection report.** • **Reference of finished product specifications.**	
377.	Name and address of manufacturer/ Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Dry Suspension (Ceph) Section.

	Brand Name + Dosage Form + Strength	CEPOSAL 40mg/5ml Oral Suspension
	Composition	Each 5ml of reconstituted suspension contains; Cefpodoxime (as proxetil)……40mg
	Diary No. Date of R & I & fee	Dy.No. 16435 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805855 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD13
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	CEFPODOXIME PROXETIL 40MG/5ML POWDER FOR ORAL SUSPENSION MHRA APPROVED.
	Me-too status	Doxicef Dry Suspension Reg. No. 045801 M/s Synchro Pharmaceuticals Lahore.
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report is required. • Reference of finished product specifications is required.
	Decision: Approved with innovator's specifications. **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
378.	Name and address of manufacturer/ Applicant	M/s. Perk Pharma(Pvt.) Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan. - (DML No. 000857) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	HICEF500mg IV Injection
	Composition	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone (USP)…..500mg
	Diary No. Date of R & I & fee	Dy. No. 16949 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0840475 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	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	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Pwder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Zetox 500mg Injection Reg. No. 053145 M/s Lahore Pharma.

	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi.	
379.	Name and address of manufacturer/ Applicant	M/s. Perk Pharma(Pvt.) Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan. - (DML No. 000857) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	HICEF 1g IV Injection
	Composition	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone (USP)…..1g
	Diary No. Date of R & I & fee	Dy. No. 16950 dated 07.03.2019. Fee paid Rs. 50,000/- dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	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	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Powder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Rocephin IV/IM Injection 1gm Reg. No. 007014 M/s Martin Dow Karachi
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi.	
380.	Name and address of manufacturer/ Applicant	M/s. Medisave Pharmaceuticals Plot No. 578-579, Sunder Industrial estate, sunder raiwind road Lahore. (DML No. 000681) (contract giver). Contract with M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore. (DML No.000801) contract acceptor Lyophilized Vials (General) Injection Section.
	Brand Name + Dosage Form + Strength	EPRAZIN 40mg Lyophilized injection
	Composition	Each vial contains; Esomeprazole Sodium Lyophilized equivalent to Esomeprazole…….40mg

	Diary No. Date of R & I & fee	Dy. No. 14981 dated 07.03.2019. Fee paid Rs. 50,000/- vide slip No. 0536174 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Proton pump inhibitors, ATC Code: A02BC05
	Type of Form	Form-5
	Finished product Specification	**MTI Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 40 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION - PL 55035/0001 MHRA APPROVED.
	Me-too status	Nexum IV 40mg Injection Reg. No. 050651 M/s Getz Pharma Karachi.
	GMP status	Last inspection of M/s MTI conducted on 09.02.2022. GMP Certificate valid till 08.02.2024 is submitted
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore and 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 07-05-2021.	
381.	Name and address of manufacturer/ Applicant	M/s. Medisave Pharmaceuticals Plot No. 578-579, Sunder Industrial estate, sunder raiwind road Lahore. (DML No. 000681) (contract giver). Contract with M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore. (DML No.000801) contract acceptor Lyophilized Vials (General) Injection Section.
	Brand Name + Dosage Form + Strength	MEPZAN 40mg Lyophilized injection
	Composition	Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole…….40mg
	Diary No. Date of R & I & fee	Dy. No. 14982 dated 07.03.2019. Fee paid Rs. 50,000/- vide slip No. 0536173 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC01
	Type of Form	Form-5
	Finished product Specification	**MTI Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion (omeprazole sodium) - PL 10622/0232 MHRA APPROVED.
	Me-too status	Risek 40mg Infusion Reg. No. 024170 M/s Getz Pharma Karachi.
	GMP status	Last inspection of M/s MTI conducted on 09.02.2022. GMP Certificate valid till 08.02.2024 is submitted
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore and 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 07-05-2021.	
382.	Name and address of manufacturer/ Applicant	M/s. Medisave Pharmaceuticals Plot No. 578-579, Sunder Industrial estate, sunder raiwind road Lahore. (DML No. 000681) (contract giver). Contract with M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore. (DML No.000801) contract acceptor Lyophilized Vials (General) Injection Section.
	Brand Name + Dosage Form + Strength	P-LINE 40mg Lyophilized injection
	Composition	Each vial contains; Pantoprazole Sodium Lyophilized equivalent to pantoprazole…….40mg
	Diary No. Date of R & I & fee	Dy. No. 14987 dated 07.03.2019. Fee paid Rs. 50,000/- vide slip No. 0536172 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Proton pump inhibitors ATC Code: A02BC02
	Type of Form	Form-5
	Finished product Specification	**MTI Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	PANTOPRAZOLE 40MG POWDER FOR SOLUTION FOR INJECTION - PL 17683/0080; UK/H/1341/001/DC MHRA Approved.
	Me-too status	Zentro Injection 045388 M/s Bosch Pharmaceutical Karachi.
	GMP status	Last inspection of M/s MTI conducted on 09.02.2022. GMP Certificate valid till 08.02.2024 is submitted
	Remarks of the Evaluator	• Innovator product contains pantoprazole as sodium sesquihydrate, in applied label sesquihydrate is not mentioned. Correction along with fee of Rs. 75000/- is required.
	Decision: Approved with innovator's specifications and following label; **Each vial contains;** **Pantoprazole Sodium sesquihydrate Lyophilized equivalent to Pantoprazole…….40mg** **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore and 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 07-05-2021.**	
383.	Name and address of manufacturer/ Applicant	M/s. Medisave Pharmaceuticals Plot No. 578-579, Sunder Industrial estate, sunder raiwind road Lahore. (DML No. 000681) (contract giver). Contract with M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore. (DML No.000801) contract acceptor

		Lyophilized Vials (General) Injection Section.
	Brand Name + Dosage Form + Strength	VANCOSAVE 500mg Lyophilized Injection
	Composition	Each vial contains; Vancomycin lyophilized as HCl…..500mg
	Diary No. Date of R & I & fee	Dy. No. 14988 dated 07.03.2019. Fee paid Rs. 50,000/- vide slip No. 0536168 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Glycopeptide antibacterials ATC Code: J01XA01
	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	VANCOMYCIN 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved.
	Me-too status	Vancomycin Injection Reg. No. 015015 M/s Abbott Laboratories Karachi.
	GMP status	Last inspection of M/s MTI conducted on 09.02.2022. GMP Certificate valid till 08.02.2024 is submitted
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore.	
384.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Amlipine 10mg/160mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine as besylate USP……..10mg Valsartan USP……160mg
	Diary No. Date of R & I & fee	Dy.No. 15465 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0825942 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code: C09DB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2x7's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	AMLODIPINE / VALSARTAN 5 MG / 80 MG, 5 MG / 160 MG AND 10 MG / 160 MG FILM-COATED TABLETS (AMLODIPINE BESILATE AND VALSARTAN) - PL 17780/0718-0720; UK/H/5856/001-3/DC MHRA APPROVED.
	Me-too status	Extor Tablet 10mg+160mg Reg. No. 054503 M/s Searle Company Ltd. Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.

	Remarks of the Evaluator	
	Decision: Approved.	
385.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Amlipine 5mg/160mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine as besylate USP……..5mg Valsartan USP……160mg
	Diary No. Date of R & I & fee	Dy.No. 15466 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0825943 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code: C09DB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2x7's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	AMLODIPINE / VALSARTAN 5 MG / 80 MG, 5 MG / 160 MG AND 10 MG / 160 MG FILM-COATED TABLETS (AMLODIPINE BESILATE AND VALSARTAN) - PL 17780/0718-0720; UK/H/5856/001-3/DC MHRA APPROVED.
	Me-too status	Extor Tablet 5mg+160mg Reg. No. 054502 M/s Searle Company Ltd. Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
386.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Amlipine 5mg/80mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine as besylate USP……..5mg Valsartan USP……80mg
	Diary No. Date of R & I & fee	Dy.No. 15428 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0801849 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code: C09DB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2x7's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	AMLODIPINE / VALSARTAN 5 MG / 80 MG, 5 MG / 160 MG AND 10 MG / 160 MG FILM-COATED TABLETS (AMLODIPINE BESILATE AND

		VALSARTAN) - PL 17780/0718-0720; UK/H/5856/001-3/DC MHRA APPROVED.
	Me-too status	Extor Tablet 5mg+80mg Reg. No. 054501 M/s Searle Company Ltd. Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
387.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	SOCALM 100mg Tablet
	Composition	Each Film Coated Tablet Contains; Quetiapine as fumarate……..100mg
	Diary No. Date of R & I & fee	Dy.No. 15414 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844323 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH04
	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	QUETIAPINE 25MG, 100MG, 150MG, 200MG AND 300MG FILM-COATED TABLETS - PL 24668/0163-7 MHRA APPROVED.
	Me-too status	Qusel 100mg Tablet Reg. no. 037685 M/s Hilton Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
388.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	SOCALM 25mg Tablet
	Composition	Each Film Coated Tablet Contains; Quetiapine as fumarate……..25mg
	Diary No. Date of R & I & fee	Dy.No. 15412 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844325 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH04
	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	QUETIAPINE 25MG, 100MG, 150MG, 200MG AND 300MG FILM-COATED TABLETS - PL 24668/0163-7 MHRA APPROVED.
	Me-too status	Qusel 25mg Tablet Reg. no. 037684

		M/s Hilton Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
389.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	SOCALOM 150mg Tablet
	Composition	Each Tablet Contains; Quetiapine as fumarate……..150mg
	Diary No. Date of R & I & fee	Dy.No. 15472 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0825949 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH04
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's. 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	QUETIAPINE 25MG, 100MG, 150MG, 200MG AND 300MG FILM-COATED TABLETS - PL 24668/0163-7 MHRA APPROVED.
	Me-too status	Could not be verified for immediate release tablet.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Product approved in RRA is film coated and me-too products are XR. Clarification or correction along with fee is required.
	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.	
390.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	DEPRIN 75mg Tablet
	Composition	Each Film Coated Tablet Contains; Bupropion hydrochloride USP…..75mg
	Diary No. Date of R & I & fee	Dy.No. 15430 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844389 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX12
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	BUPROPION HYDROCHLORIDE 75MG ORAL TABLET, APOTEX INC USFDA APPROVED.
	Me-too status	Smokik 75mg Tablet 75mg Reg. No. 035774 M/s Hilton Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is

		good.
	Remarks of the Evaluator	
	Decision: Approved.	
391.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	DEPRIN XL 150mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains; Bupropion hydrochloride USP…..150mg
	Diary No. Date of R & I & fee	Dy.No. 15442 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811900 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX12
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ZYBAN 150 MG PROLONGED RELEASE TABLETS MHRA APPROVED.
	Me-too status	Ropion Tablet 150mg Reg. No. 037112 M/s martin Dow Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
392.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OZINE 5mg Tablet
	Composition	Each Film Coated Tablet Contains; Olanzapine (USP)……..5mg
	Diary No. Date of R & I & fee	Dy.No. 15487 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901910 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	OLANZAPINE 2.5 MG, 5 MG, 7.5 MG, 10 MG, 15 MG AND 20 MG TABLETS - PL 32854/0015-20 (FILM COATED) MHRA APPROVED.
	Me-too status	Lepinza 5mg Tablet Reg. No. 061302 M/s Nexus Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	

393.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OZINE 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Olanzapine (USP)……..10mg
	Diary No. Date of R & I & fee	Dy.No. 15485 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901908 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	OLANZAPINE 2.5 MG, 5 MG, 7.5 MG, 10 MG, 15 MG AND 20 MG TABLETS - PL 32854/0015-20 (FILM COATED) MHRA APPROVED.
	Me-too status	Lepinza 10mg Tablet Reg. No. 061303 M/s Nexus Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
394.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	OZINE-F 6mg+25mg Capsule
	Composition	Each capsule contains; Olanzapine (USP)……..6mg Fluoxetine as Hydrochloride (USP)….25mg
	Diary No. Date of R & I & fee	Dy.No. 15453 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844511 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Antidepressent combination with antipsychotic.
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	SYMBYAX CAPSULES USFDA APPROVED.
	Me-too status	Co-depricap 6/25 capsule Reg. No. 076135 M/s Nabiqasim Industries Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
395.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.

	Brand Name + Dosage Form + Strength	NEUGABA 100mg Capsule
	Composition	Each capsule contains; Pregabalin (USP)…….100mg
	Diary No. Date of R & I & fee	Dy.No. 15451 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844509 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PREGABALIN NOUMED 25, 50, 75, 100, 150, 200, 225 AND 300MG CAPSULES, HARD (PREGABALIN) - PL 44041/0065-0072 MHRA APPROVED.
	Me-too status	Gabica 100 mg Capsule Reg. No. 047366 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications. **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 07-05-2021, before issuance of registration letter.**	
396.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	NEUGABA 50mg Capsule
	Composition	Each capsule contains; Pregabalin (USP)…….50mg
	Diary No. Date of R & I & fee	Dy.No. 15450 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844508 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PREGABALIN NOUMED 25, 50, 75, 100, 150, 200, 225 AND 300MG CAPSULES, HARD (PREGABALIN) - PL 44041/0065-0072 MHRA APPROVED.
	Me-too status	Gabica 50 mg Capsule Reg. No. 048725 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications. **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 07-05-2021, before issuance of registration letter.**	

397.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	NEUGABA 75mg Capsule
	Composition	Each capsule contains; Pregabalin (USP)…….75mg
	Diary No. Date of R & I & fee	Dy.No. 15452 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844510 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PREGABALIN NOUMED 25, 50, 75, 100, 150, 200, 225 AND 300MG CAPSULES, HARD (PREGABALIN) - PL 44041/0065-0072 MHRA APPROVED.
	Me-too status	Gabica 75 mg Capsule Reg. No. 047365 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications. **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 07-05-2021, before issuance of registration letter.**	
398.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	NEBINOR 2.5mg Tablet
	Composition	Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)…..2.5mg
	Diary No. Date of R & I & fee	Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Beta blocking agents, selective ATC Code: C07AB12
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED.
	Me-too status	Nebix 2.5mg Tablet Reg. No. 062776 M/s Highnoon Laboratories Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
399.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	N-PRAM 10mg Tablet
	Composition	Each film coated tablet contains;

		Escitalopram as oxalate……10mg
	Diary No. Date of R & I & fee	Dy.No. 15417 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844320 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL 36390/0149-51; UK/H/5394/001-3/DC) MHRA Approved.
	Me-too status	Cipralex Film-Coated Tablet 10mg Reg. No. 028467 M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
400.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	N-PRAM 10mg Tablet
	Composition	Each film coated tablet contains; Escitalopram as oxalate……10mg
	Diary No. Date of R & I & fee	Dy.No. 15417 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844320 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL 36390/0149-51; UK/H/5394/001-3/DC) MHRA Approved.
	Me-too status	Cipralex Film-Coated Tablet 10mg Reg. No. 028467 M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
401.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	DAXUM 60mg Capsule
	Composition	Each capsule contains; Duloxetine as enteric coated pellets 17% (USP)…60mg
	Diary No. Date of R & I & fee	Dy.No. 15449 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844507 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX21
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	DULOXETINE 60 MG GASTRO-RESISTANT CAPSULES, HARD - PL 49445/0097 MHRA Approved.
	Me-too status	Lyta 60mg Capsule Reg. No. 066918 M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.

	Remarks of the Evaluator	• Source of pellets is required.
	Decision: Approved. The firm shall submit source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets before issuance of registration letter.	
402.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	DAXUM 30mg Capsule
	Composition	Each capsule contains; Duloxetine as enteric coated pellets 17% (USP)…30mg
	Diary No. Date of R & I & fee	Dy.No. 15448 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844506 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX21
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	DULOXETINE 30 MG GASTRO-RESISTANT CAPSULES, HARD - PL 49445/0095 MHRA Approved.
	Me-too status	Lyta 30mg Capsule Reg. No. 066917 M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Source of pellets is required.
	Decision: Approved. The firm shall submit source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets before issuance of registration letter.	
403.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	LACOMIDE 50mg Tablet
	Composition	Each film coated tablet contains; Lacosamide ……50mg
	Diary No. Date of R & I & fee	Dy.No. 15432 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844400 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX18
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved.
	Me-too status	Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
404.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	LACOMIDE 100mg Tablet
	Composition	Each film coated tablet contains; Lacosamide ……100mg

	Diary No. Date of R & I & fee	Dy.No. 15431 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844399 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX18
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LACOSAMIDE AMAROX 100 MG FILM-COATED TABLETS - PL 49445/0082 MHRA Approved.
	Me-too status	Lacoste 100mg Tablet Reg. No. 086630 M/s Scilife Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
405.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	FESAT 40mg Tablet
	Composition	Each Film Coated Tablet Contains; Febuxostat……..40mg
	Diary No. Date of R & I & fee	Dy.No. 16411 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901933 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Preparations inhibiting uric acid production ATC Code: M04AA03
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Uloric tablets 40 mg. FDA Approved.
	Me-too status	Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
406.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	FESAT 80mg Tablet
	Composition	Each Film Coated Tablet Contains; Febuxostat……..80mg
	Diary No. Date of R & I & fee	Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Preparations inhibiting uric acid production ATC Code: M04AA03
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Uloric tablets 80 mg. USFDA Approved.
	Me-too status	Adenuric Tablet 80mg Reg. No. 067034 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi.

	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
407.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MIRNTE 30mg Tablet
	Composition	Each Film Coated Tablet Contains; Mirtazapine USP……..30mg
	Diary No. Date of R & I & fee	Dy.No. 15461 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844519 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX11
	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	Mirtazapine 15 mg, 30 mg and 45 mg film-coated tablets - PL 28444/0097-9 MHRA Approved.
	Me-too status	Mezeron 30mg Tablet Reg. No. 026397 M/s OBS Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
408.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OLMEZEST 20mg/5mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine as Besylate USP……5mg Olmesartan medoximil USP……20mg
	Diary No. Date of R & I & fee	Dy.No. 15490 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901913 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers. ATC Code: C09DB02
	Type of Form	Form-5
	Finished product Specification	**In-House Specs**
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Olmesartan medoxomil and Amlodipine 20mg/5mg, 40mg/5mg & 40mg/10mg film-coated tablets PL 51718/0032-0034 MHRA Approved.
	Me-too status	Baritec-A 20/5mg Tablet Reg. No. 081442 M/s Barrett Hodgson Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
409.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OLMEZEST 40mg/5mg Tablet
	Composition	Each Film Coated Tablet Contains;

		Amlodipine as Besylate USP……5mg Olmesartan medoximil USP……40mg
	Diary No. Date of R & I & fee	Dy.No. 15488 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901911 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers. ATC Code: C09DB02
	Type of Form	Form-5
	Finished product Specification	**In-House Specs**
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Olmesartan medoxomil and Amlodipine 20mg/5mg, 40mg/5mg & 40mg/10mg film-coated tablets PL 51718/0032-0034 MHRA Approved.
	Me-too status	Baritec-A 40/5mg Tablet Reg. No. 081443 M/s Barrett Hodgson Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
410.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OLMEZEST 20mg/10mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine as Besylate USP……10mg Olmesartan medoximil USP……20mg
	Diary No. Date of R & I & fee	Dy.No. 15489 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901912 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers. ATC Code: C09DB02
	Type of Form	Form-5
	Finished product Specification	**In-House Specs**
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	AZOR 10mg/20mg Tablet USFDA Approved.
	Me-too status	Omsana-AM 10/20 Tablet Reg. No. 058559 M/s Hilton Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
411.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	PAROXID CR Tablet 12.5mg
	Composition	Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.12.5mg
	Diary No. Date of R & I & fee	Dy.No. 15421 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844316 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB05
	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	PAXIL CR 12.5mg tablet Extended release USFDA Approved.
	Me-too status	Seroxat CR Tablet 12.5mg Reg. No. 043058 M/s GSK Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
412.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	PAROXID CR Tablet 37.5mg
	Composition	Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.37.5mg
	Diary No. Date of R & I & fee	Dy.No. 15419 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844318 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB05
	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	PAXIL CR 37.5mg tablet Extended release USFDA Approved.
	Me-too status	Paraxyl CR Tablet 37.5mg Reg. No. 060323 M/s GSK Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
413.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	PAROXID CR Tablet 25mg
	Composition	Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.25mg
	Diary No. Date of R & I & fee	Dy.No. 15420 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844317 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB05
	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	PAXIL CR 25mg tablet Extended release USFDA Approved.
	Me-too status	Zara 25mg Reg. No. 069192 M/s Shrooq Pharma Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
414.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule (general) Section.
	Brand Name + Dosage Form + Strength	Aquanor 10ml WFI
	Composition	Each 10ml Ampoule Contain; Water for injection……..10ml
	Diary No. Date of R & I & fee	Dy.No. 16425 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901949 dated 06.03.2019, endorsed on 07.03.2019

	Pharmacological Group	NA
	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	NA
	Me-too status	NA
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
415.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule (general) Section.
	Brand Name + Dosage Form + Strength	Aquanor 10ml WFI
	Composition	Each 10ml Ampoule Contain; Water for injection……..10ml
	Diary No. Date of R & I & fee	Dy.No. 16425 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901949 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	NA
	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	Sterilised Water for Injections - PL 01502/0069 MHRA Approved.
	Me-too status	Sterile water for injection 10ml Reg. No. 053043 M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
416.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	VIOMET 50mg/1000mg Tablet
	Composition	Each film coated tablet contains Contain; Vidagliptin ……..…50mg Metformin HCl USP…1000mg
	Diary No. Date of R & I & fee	Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Velon-M Tablet Reg. No. 084692 M/s Genix Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
417.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792)

		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	VIOMET 50mg/850mg Tablet
	Composition	Each film coated tablet contains Contain; Vidagliptin ……..…50mg Metformin HCl USP…850mg
	Diary No. Date of R & I & fee	Dy.No. 15410 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844327 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	VILDAGLIPTIN/METFORMIN 50 MG/850 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Velon-M Tablet Reg. No. 074866 M/s Genix Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
418.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	SIOMET 50mg/1000mg Tablet
	Composition	Each film coated tablet contains Contain; Sitagliptin phosphate monohydrate….50mg Metformin HCl……..……..1000mg
	Diary No. Date of R & I & fee	Dy. No. 15411 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844326 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD07
	Type of Form	Form-5
	Finished product Specification	**In-House**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Janumet Tablets MHRA Approved.
	Me-too status	Treviamet 50mg 1000mg Tablet Reg. No. 055444 M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. 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 07-05-2021, before issuance of registration letter.	
419.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Capsule 250mg
	Composition	Each capsule contains; Tranexamic Acid..…….250mg
	Diary No. Date of R & I & fee	Dy. No. 16384 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900233 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	Type of Form	Form-5

	Finished product Specification	BP **Specifications (couldn't be found in BP, available in JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed in capsule dosage form
	Me-too status	Melaxic 250mg Capsule Reg. No. 113136 M/s Crystolite Pharmaceuticals.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Evidence of RRA approval of product in Capsule dosage form is required.
	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.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
420.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Capsule 500mg
	Composition	Each capsule contains; Tranexamic Acid..…….500mg
	Diary No. Date of R & I & fee	Dy. No. 16376 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900221 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	Type of Form	Form-5
	Finished product Specification	BP **Specifications (couldn't be found in BP, available in JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed in capsule dosage form
	Me-too status	Melaxic 500mg Capsule Reg. No. 113137 M/s Crystolite Pharmaceuticals.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Evidence of RRA approval of product in Capsule dosage form is required.
	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.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
421.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Injection 1g
	Composition	Each 5ml (ampoule) contains; Tranexamic Acid..……1g
	Diary No. Date of R & I & fee	Dy. No. 16383 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900232 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	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	Could not be confirmed in 1g/5ml Injection dosage form
	Me-too status	Transolide Injection 1g Reg. No. 068820 M/s Global Pharmaceuticals.
	GMP status	Certificate of 2018 is submitted.

	Remarks of the Evaluator	• Evidence of RRA approval of formulation is required.
	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.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
422.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Injection 500mg
	Composition	Each 5ml (ampoule) contains; Tranexamic Acid..…….500mg
	Diary No. Date of R & I & fee	Dy. No. 16381 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900229 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	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	TRANEXAMIC ACID 100 MG/ML SOLUTION FOR INJECTION MHRA Approved
	Me-too status	Transager Injection 500mg Reg. No. 110986 M/s Allmed (Pvt.) Ltd.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Evidence of RRA approval of formulation is required.
	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.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
423.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tamsin Capsule 0.4mg
	Composition	Each capsule contains; Tamsulosin Hydrochloride..…….0.4mg
	Diary No. Date of R & I & fee	Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	G04CA02 Alpha-adrenoreceptor 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	FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved
	Me-too status	Soltim Capsule Reg. No. 111055 M/s Medisynth Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Section Approval is required. • Revised label claim as per RRAs along with fee of Rs. 30000/- is required.
	Decision: Deferred for following; • **Revision of label as per innovator product.** • **Section approval letter.**	

	• **Latest GMP inspection report/ certificate.**	
424.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tamsin-D Capsule 0.5mg/0.4mg
	Composition	Each capsule contains; Dutasteride……0.5mg Tamsulosin Hydrochloride..…….0.4mg
	Diary No. Date of R & I & fee	Dy. No. 16385 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900234 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	G04CA52 Alpha-adrenoreceptor 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	DUTASTERIDE/TAMSULOSIN 0.5/0.4 MG HARD CAPSULES MHRA Approved
	Me-too status	Maxflo-D Capsule Reg. No. 091571 M/s CCL Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Section Approval is required. • Revised label claim as per RRAs along with fee of Rs. 30000/- is required.
	Decision: Deferred for following; • **Revision of label as per innovator product.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
425.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Injection 250mg
	Composition	Each 5ml (ampoule) contains; Tranexamic Acid……..250mg
	Diary No. Date of R & I & fee	Dy. No. 16380 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901900 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	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	Could not be verified for strength of 250mg
	Me-too status	Transamin Injection 250mg Reg. No. 007534
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Evidence of RRA approval of formulation is required.
	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.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
426.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Ipralog-40 Injection
	Composition	Each 1ml suspension (ampoule) contains; Triamcinolone Acetonide……..40mg

	Diary No. Date of R & I & fee	Dy. No. 16377 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900222 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	H02AB08 CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN
	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	KENALOG INTRA-ARTICULAR/INTRAMUSCULAR INJECTION 40MG/ML MHRA Approved
	Me-too status	Kenatex 40mg Reg. No. 097783 M/s Rotex Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Deferred for following; • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
427.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Neo-Rolate 0.5mg/2.5mg Injection
	Composition	Each ampoule contains: Glycopyrrolate……..0.5mg Neostigmine Sulphate….2.5mg
	Diary No. Date of R & I & fee	Dy. No. 16379 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900224 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N07AA51 Anticholinesterases, combinations
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	GLYCOPYRRONIUM BROMIDE 0.5MG/ML AND NEOSTIGMINE METILSULFATE 2.5MG/ML SOLUTION FOR INJECTION MHRA Approved
	Me-too status	Elektra Injection Reg. No. 111728 M/s Rotex Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Revised label claim as per RRAs along with fee of Rs. 30000/- is required. • Reference of finished product specifications is required.
	Decision: Deferred for following; • **Revision of label as per innovator product.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
428.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Itrocap Capsule 100mg
	Composition	Each capsule contains: Itraconazole……100mg
	Diary No. Date of R & I & fee	Dy. No. 16382 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900231 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J02AC02 Triazole and tetrazole derivatives

	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	Itraconazole 100mg Capsules, hard MHRA Approved.
	Me-too status	Sporanox Capsule Reg. No. 012647 M/s Aspin Pharma (pvt.) Ltd. Karachi.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Revised label claim as per RRAs along with fee of Rs. 30000/- is required.
	Decision: Deferred for following; • **Revision of label as per innovator product.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
429.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tradol Injection
	Composition	Each ampoule contains: Tramadol HCl……50mg
	Diary No. Date of R & I & fee	Dy. No. 16378 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900223 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N02AX02 Other opioids
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Provided reference is of 100mg Injection.
	Me-too status	Tamadol 50mg Injection Reg. No. 110692 M/s Highnoon Laboratories
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Evidence of RRA approval of formulation in 50ml packaging is required. • Reference of finished product specifications is required.
	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.** • **Section approval letter.** • **Latest GMP inspection report/ certificate.**	
430.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S.-3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Furmid Injection 20mg
	Composition	Each ampoule contains: Furosemide……20mg
	Diary No. Date of R & I & fee	Dy. No. 16387 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900219 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C03CA01 Sulfonamides, plain
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications (found in BP, USP & JP)**
	Pack size & Demanded Price	As per SRO.

	Approval status of product in Reference Regulatory Authorities	Furosemide 20mg/2ml Solution for Injection. MHRA Approved
	Me-too status	Lasix Injection 20mg Reg. No. 000230 M/s Sanofi-Aventis Pakistan Ltd. Karachi.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Reference of finished product specifications is required.
	Decision: Deferred for following; • **Reference of finished product specifications.** • **Latest GMP inspection report/ certificate.** • **Section approval letter.**	
431.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Losin Capsule 0.2mg
	Composition	Each capsule contains: Tamsulosin HCl (as sustained release pellets)……0.2mg
	Diary No. Date of R & I & fee	Dy. No. 13497 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0833287 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	G04CA02 Alpha-adrenoreceptor 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	PMDA Approved
	Me-too status	Xhyva SR Capsule 0.2mg Reg. No. 110142 M/s MKB Pharma.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Source of pellets is required.
	Decision: Deferred for following; • **Source of pellets.** • **Latest GMP inspection report/ certificate.**	
432.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Losin Suspension 0.4mg
	Composition	Each 5ml contains: Tamsulosin HCl……0.4mg
	Diary No. Date of R & I & fee	Dy. No. 13499 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0833289 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	G04CA02 Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Not Found
	Me-too status	Not Found
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Evidence of RRA approval of formulation is required. • Evidence of availability of Me-too is required.
	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.** • **Latest GMP inspection report/ certificate.** • **Section approval letter.**	
433.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Glipx Tablet 2.5mg
	Composition	Each film-coated tablet contains: Saxagliptin as HCl……2.5mg
	Diary No. Date of R & I & fee	Dy. No. 13486 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844121 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BH03 Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Onglyza 2.5 mg film-coated tablets MHRA Approved
	Me-too status	Saglip 2.5mg Tablet Reg. No. 071487. Mfg. by M/s CCL Lahore.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Deferred for following; • **Latest GMP inspection report/ certificate.** • **Clarification of salt form of the drug substance with reference to the innovator product.**	
434.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Glipx Tablet 5mg
	Composition	Each film-coated tablet contains: Saxagliptin as HCl……5mg
	Diary No. Date of R & I & fee	Dy. No. 13485 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844120 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BH03 Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Saglip 5mg Tablet Reg. No. 071486. Mfg. by M/s CCL Lahore.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Deferred for following; • **Latest GMP inspection report/ certificate.** • **Clarification of salt form of the drug substance with reference to the innovator product.**	
435.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Colicit Tablet 500mg
	Composition	Each film-coated tablet contains: Citicoline as Sodium……500mg
	Diary No. Date of R & I & fee	Dy. No. 13488 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844123 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06BX06 Other psychostimulants and nootropics

	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Not Found
	Me-too status	Not Found
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Evidence of RRA approval of formulation is required. • Evidence of availability of Me-too in film-coating is required.
	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.** • **Latest GMP inspection report conducted within last three years.**	
436.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Colicit Syrup 500mg/5ml
	Composition	Each 5ml contains: Citicoline as Sodium……500mg
	Diary No. Date of R & I & fee	Dy. No. 13496 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844050 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06BX06 Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	**In-house 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	Citicode Syrup by Rotex Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years.** • **Section approval letter.**	
437.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Tin Tablet 1mg
	Composition	Each Film-coated tablet contains: Pitavastatin as Calcium……1mg
	Diary No. Date of R & I & fee	Dy. No. 13478 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844006 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C10AA08 HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications (found in JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ALIPZA 1MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Pinstatin 1mg Reg. No. 107112 by Moringa Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Reference of finished product specifications is required.

	Decision: Approved with JP specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021 before issuance of registration letter.	
438.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Tin Tablet 2mg
	Composition	Each Film-coated tablet contains: Pitavastatin as Calcium……2mg
	Diary No. Date of R & I & fee	Dy. No. 13479 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844007 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C10AA08 HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications (found in JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ALIPZA 2MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Pinstatin 2mg Reg. No. 107113 by Moringa Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Reference of finished product specifications is required.
	Decision: Approved with JP specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021 before issuance of registration letter.	
439.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Tin Tablet 4mg
	Composition	Each Film-coated tablet contains: Pitavastatin as Calcium……4mg
	Diary No. Date of R & I & fee	Dy. No. 13480 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844008 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C10AA08 HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications (found in JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ALIPZA 4MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Pinstatin 4mg Reg. No. 107114 by Moringa Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Reference of finished product specifications is required.
	Decision: Approved with JP specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021 before issuance of registration letter.	
440.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Ronol Tablet 80mg
	Composition	Each Film-coated tablet contains: Hydrated Phloroglucinol…..80mg corresponding to anhydrous Phloroglucinol……62.233mg
	Diary No. Date of R & I & fee	Dy. No. 16440 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0833290 dated 07-03-2019, endorsed on 07.03.2019.

	Pharmacological Group	A03AX12 Other drugs for functional gastrointestinal disorders
	Type of Form	Form-5
	Finished product Specification	**In-house**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Not Found
	Me-too status	Not found
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Evidence of RRA approval of formulation is required. • Evidence of availability of Me-too is required.
	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.** • **Latest GMP inspection report/ certificate.**	
441.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Ronol Suspension 80mg
	Composition	Each 5ml contains: Hydrated Phloroglucinol…..80mg
	Diary No. Date of R & I & fee	Dy. No. 16441 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0833291 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A03AX12 Other drugs for functional gastrointestinal disorders
	Type of Form	Form-5
	Finished product Specification	**In-house**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Not Found
	Me-too status	Not found
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Evidence of RRA approval of formulation is required. • Evidence of availability of Me-too is required.
	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.** • **Latest GMP inspection report/ certificate.**	
442.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Get Tablet 8mg
	Composition	Each Film-coated tablet contains: Ondansetron Hydrochloride Dihydrate eq. to Ondansetron……8mg
	Diary No. Date of R & I & fee	Dy. No. 13484 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844119 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A04AA01 Serotonin (5HT3) antagonists
	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	Ondansetron 8 mg (Ondansetron Hydrochloride dihydrate) MHRA Approved.

	Me-too status	Zofran Tablets 8 mg Reg. No. 020668 M/s GSK Karachi.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years along before issuance of registration letter.	
443.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	PIO-G Tablet 30mg/2mg
	Composition	Each tablet contains: Pioglitazone as HCl……30mg Glimepiride……..2mg
	Diary No. Date of R & I & fee	Dy. No. 13481 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844009 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BD06 Combinations of oral blood glucose lowering drugs
	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	Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/2 mg uncoated tablet) FDA Approved
	Me-too status	Piozer-G 30/2 Tablets Reg. No. 050690 M/s Hilton Pharma (Pvt) Ltd,, 13, Sector-15, Korangi Industrial Area, Karachi
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years along before issuance of registration letter.	
444.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	PIO-G Tablet 30mg/4mg
	Composition	Each tablet contains: Pioglitazone as HCl……30mg Glimepiride……..4mg
	Diary No. Date of R & I & fee	Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BD06 Combinations of oral blood glucose lowering drugs
	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	Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved
	Me-too status	Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd,, 13, Sector-15, Korangi Industrial Area, Karachi
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years along before issuance of registration letter.	
445.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	GLIP Tablet 5mg

	Composition	Each film-coated tablet contains: Linagliptin……..5mg
	Diary No. Date of R & I & fee	Dy. No. 13487 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844122 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BH05 Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	LINAGLIPTIN 5 MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Encylin 5mg Tablets Reg. No. 110863 M/s Jenner Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Approved with Innovator's Specifications. Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.	
446.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Capsule Section (general)
	Brand Name + Dosage Form + Strength	Gaybal Capsule 150mg
	Composition	Each capsule contains: Pregabalin……..150mg
	Diary No. Date of R & I & fee	Dy. No. 13477 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844005 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N02BF02 Gabapentinoids
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications (found in BP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Pregabalin Noumed 25, 50, 75, 100, 150, 200, 225 and 300mg Capsules, hard (pregabalin) - PL 44041/0065-0072 MHRA Approved.
	Me-too status	Gabica 150 mg Capsule Reg. No. 048724 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with BP Specifications. **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
447.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Oral dry powder suspension (general)
	Brand Name + Dosage Form + Strength	Clear Suspension 5mg/5ml

	Composition	Each 5ml after reconstitution contains: Montelukast as Sodium……..5mg
	Diary No. Date of R & I & fee	Dy. No. 13498 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0833288 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	R03DC03 Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Provided reference is of sachet
	Me-too status	Synkast Dry Suspension Reg. No. 076929 M/s Synchro Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Evidence of RRA approval of formulation in bottle packing is required.
	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.** • **Latest GMP inspection report/ certificate conducted within last three years.**	
448.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Cis Capsule 375mg
	Composition	Each hard gelatin capsule contains: Carbocisteine……..375mg
	Diary No. Date of R & I & fee	Dy. No. 13490 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844125 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	R05CB03 Mucolytics
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	CARBOCISTEINE 375MG CAPSULES MHRA Approved
	Me-too status	Carbex Capsule Reg. No. 075962 M/s Platinum Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's Specifications. **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
449.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Capsule (general) Section.

	Brand Name + Dosage Form + Strength	CETA Capsule 400mg
	Composition	Each hard gelatin capsule contains: Piracetam……..400mg
	Diary No. Date of R & I & fee	Dy. No. 13491 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844126 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06BX03 Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Ucetam Capsule Reg. No. 021955 M/s Al-Habib Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate 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.	
450.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Oral liquid general section.
	Brand Name + Dosage Form + Strength	Levecetam Oral Solution 100mg/ml
	Composition	Each ml contains: Levetiracetam……..100mg
	Diary No. Date of R & I & fee	Dy. No. 13493 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844047 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N03AX14 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications (found in USP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	LEVETIRACETAM CRESCENT 100 MG/ML ORAL SOLUTION MHRA Approved
	Me-too status	Lecetam Oral Solution Reg. No. 112608 M/s Indus Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP Specifications. **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
451.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Capsule (general) Section.

	Brand Name + Dosage Form + Strength	Cool Capsule 4mg
	Composition	Each hard gelatin capsule contains: Thiocolchicoside……..4mg
	Diary No. Date of R & I & fee	Dy. No. 13492 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844127 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M03BX05 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MIOREL 4 mg, capsule ANSM France Approved
	Me-too status	Thiolax Capsule by S.J&G Fazul Ellahie
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's Specifications. **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
452.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Tablet general Section.
	Brand Name + Dosage Form + Strength	T-SART Plus Tablet 80mg/12.5mg
	Composition	Each tablet contains: Telmisartan……..80mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R & I & fee	Dy. No. 13483 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844118 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C09DA07 Angiotensin II receptor blockers (ARBs) and diuretics
	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	TELMISARTAN AND HYDROCHLOROTHIAZIDE CRESENT 80MG/12.5MG TABLETS MHRA Approved
	Me-too status	Elsart-H Reg. No. 112705 M/s High-Q Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/inspection report.	
453.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Capsule (general) Section.

	Brand Name + Dosage Form + Strength	ERD Capsule 150mg
	Composition	Each hard gelatin capsule contains: Erdosteine……150mg
	Diary No. Date of R & I & fee	Dy. No. 13495 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844049 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	R05CB15 Mucolytics
	Type of Form	Form-5
	Finished product Specification	**Inhouse Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ERDOTIN 150 MG CAPSULE RIGIDE. AIFA approved
	Me-too status	Dostin Capsules 150mg. Reg. No. 032332
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's Specifications. **Firm shall submit latest GMP inspection report conducted within last three years along with 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 07-05-2021, before issuance of registration letter.**	
454.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Topical (steroid) Section.
	Brand Name + Dosage Form + Strength	Dermasol Cream 0.05%
	Composition	Each gram contains: Clobetasol Propionate……0.5mg
	Diary No. Date of R & I & fee	Dy. No. 13692 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901274 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D07AD01 Corticosteroids, very potent (group IV)
	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	Clobetasol Propionate 0.05% w/w Ointment (PL17507/00236) MHRA Approved.
	Me-too status	Clobetol ointment 0.05% Reg. No. 065177 M/s Valor Pharmaceuticals Islamabad
	GMP status	report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
455.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Capsule(general) section.
	Brand Name + Dosage Form + Strength	Cymol Capsule 30mg

	Composition	Each hard gelatin capsule contains: Duloxetine Hydrochloride (as Enteric Coated Pellets) eq. to Duloxetine……30mg
	Diary No. Date of R & I & fee	Dy. No. 13683 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901264 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06AX21 Other antidepressants
	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	Dulan Capsule by Hilton
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Source of Pellets is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter along with of documents for source of pellets along with requisite fee (in case of imported source).	
456.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Paroxilex CR Tablet 12.5mg
	Composition	Each extended release tablet contains: Paroxetine as Hydrochloride……12.5mg
	Diary No. Date of R & I & fee	Dy. No. 13798 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0817898 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06AB05 Selective serotonin reuptake inhibitors
	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	PAXIL CR, Paroxetine hydrochloride (eq to base: 12.5mg, 25mg, 37.5mg) tablet extended release. USFDA Approved.
	Me-too status	Seroxat CR tablet 12.5mg Reg. No. 043058 M/s GSK Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
457.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Paroxilex CR Tablet 25mg
	Composition	Each extended release tablet contains: Paroxetine as Hydrochloride……25mg

	Diary No. Date of R & I & fee	Dy. No. 13799 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0817899 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06AB05 Selective serotonin reuptake inhibitors
	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	PAXIL CR, Paroxetine hydrochloride (eq to base: 12.5mg, 25mg, 37.5mg) tablet extended release. USFDA Approved.
	Me-too status	Seroxat CR tablet 25mg Reg. No. 043059 M/s GSK Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
458.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Paroxilex CR Tablet 37.5mg
	Composition	Each extended release tablet contains: Paroxetine as Hydrochloride……37.5mg
	Diary No. Date of R & I & fee	Dy. No. 13800 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0817900 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06AB05 Selective serotonin reuptake inhibitors
	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	PAXIL CR, Paroxetine hydrochloride (eq to base: 12.5mg, 25mg, 37.5mg) tablet extended release. USFDA Approved.
	Me-too status	Xtin CR tablet 37.5mg Reg. No. 112923 M/s Siam Pharma.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
459.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Lacosa Tablet 100mg
	Composition	Each film-coated tablet contains: Lacosamide……100mg
	Diary No. Date of R & I & fee	Dy. No. 13689 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901271 dated 07-03-2019, endorsed on

		07.03.2019.
	Pharmacological Group	N03AX18 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**As per Innovator (found in BP, USP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP Specifications. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter and 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.	
460.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Lacosa Tablet 150mg
	Composition	Each film-coated tablet contains: Lacosamide……150mg
	Diary No. Date of R & I & fee	Dy. No. 13690 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901272 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N03AX18 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**As per Innovator (found in BP, USP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP Specifications. Registration letter shall be issued after submission of latest GMP certificate/inspection report and fee of Rs. 7500/- as per SRO496(I)/2023 dated 17.04.2023.	
461.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) section.
	Brand Name + Dosage Form + Strength	Doxofin Tablet 400mg
	Composition	Each tablet contains: Doxofylline……400mg
	Diary No. Date of R & I & fee	Dy. No. 13700 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901283 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	R03DA11 Xanthines
	Type of Form	Form-5

	Finished product Specification	**As per Innovator**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	AIFA Italy Approved
	Me-too status	Xofi Tablet by Hilton
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/inspection report.	
462.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Pain-Go Tablet 4mg
	Composition	Each film-coated tablet contains: Lornoxicam……4mg
	Diary No. Date of R & I & fee	Dy. No. 13684 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901265 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AC05 Oxicams
	Type of Form	Form-5
	Finished product Specification	**In-house Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Xefo 4mg film-coated tablet (EMA approved)
	Me-too status	Xonica 4mg Tablet by M/s Zephyr Pharmatec (Reg#086984)
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/inspection report.	
463.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Ariper Tablet 10mg
	Composition	Each tablet contains: Aripiprazole……15mg
	Diary No. Date of R & I & fee	Dy. No. 13805 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900298 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N05AX12 Other antipsychotics
	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	Aripiprazole 5, 10, 15 and 30 mg tablets (aripiprazole) - PL 24837/0050-0053; UK/H/5676/001-004/DC MHRA Approved.

	Me-too status	Mactril tablet 15mg Reg. No. 067735 M/s Wilshire Laboratories Lahore.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Correction of strength is required along with fee of Rs. 30000/- as brand name indicates 10mg while composition indicates 15mg strength.
	Decision: Deferred for following; • **Latest GMP inspection report conducted within last three years.** • **Clarification of applied strength and label.**	

Differential fee cases

464.	Name and address of manufacturer/ Applicant	M/s Pacific Pharmaceuticals Ltd. 30KM Multan Road, Lahore (DML No. 000295) Topical cream/ ointment/ Gel (general) Section.
	Brand Name + Dosage Form + Strength	Ismagel 0.05% Gel
	Composition	Each 100gm contains; Isotretinoin……50mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 4778 dated 27.4.2011 R&I verified. Initial fee Rs. 8000/- endorsed on 26.04.2011. Differential fee: Fee paid Rs. 12000/- vide Slip No. 0081291 dated 20-10-2014. Duplicate Dossier: Dy No. 32481 dated 11.11.2022
	Pharmacological Group	Retinoids for topical use in acne ATC Code: D10AD04
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (monograph in BP)**
	Pack size & Demanded Price	10g. Rs. 250/-.
	Approval status of product in Reference Regulatory Authorities	Isotrex Gel isotretinoin 0.05% w/w (0.05 g per 100 g gel). MHRA Approved.
	Me-too status	Isotin gel Reg. No. 041923 M/s Shaigan Pharmaceutical (Pvt.) ltd. Rawalpindi.
	GMP status	Inspection conducted on 14.09.2021. GMP status is good.
	Remarks of the Evaluator	i. Reference of finished product specifications is not provided.
	Decision: Approved with BP Specifications. 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 07-05-2021, before issuance of registration letter.	
465.	Name and address of manufacturer/ Applicant	M/s Pacific Pharmaceuticals Ltd. 30KM Multan Road, Lahore (DML No. 000295) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Melomin XR 500mg Tablet
	Composition	Each extended release tablet contains; Metformin HCl……500mg
	Diary No. Date of R & I & fee	Initial dossier submission:

		Dy. No. 4777 dated 27.4.2011 R&I verified. Initial fee Rs. 15000/- endorsed on 07.04.2011. Differential fee: Fee paid Rs. 5000/- vide Slip No. 0784135 dated 23-10-2018, endorsement 25.10.2018. Duplicate Dossier: Dy No. 32483 dated 11.11.2022
	Pharmacological Group	Biguanides ATC Code: A10BA02
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (monograph in USP)**
	Pack size & Demanded Price	10g. Rs. 250/-.
	Approval status of product in Reference Regulatory Authorities	Metformin Teva SR 500 mg, 750 mg and 1000 mg prolonged-release tablets (metformin hydrochloride) - PL 00289/2159-2161; UK/H/6844/001-03/DC MHRA Approved.
	Me-too status	Glucophage XR Tablet 500mg Reg. No. 109987 M/s Martin Dow Marker Ltd Quetta.
	GMP status	Inspection conducted on 14.09.2021. GMP status is good.
	Remarks of the Evaluator	i. Reference of finished product specifications is not provided.
	Decision: Approved with USP Specifications. 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 07-05-2021, before issuance of registration letter.	

Agenda of Evaluator PEC-X

Case no. 01 Registration applications of newly granted DML (Veterinary)

a. New Cases

I. M/s Acme Pharmaceuticals, Rawat, Islamabad.

CLB in its 289th meeting held on 23rd January, 2023 has considered and approved the grant of DML by way of formulation with following sections.

1. **Oral Dry Powder-I**
2. **Oral Dry Powder-II**
3. **Oral Liquid-I**
4. **Oral Liquid-II**

Accordingly, firm has applied for following products for consideration by the Registration Board.

Section	No. of Products applied	No. of Molecules applied
Oral Liquid-I	30	10
Oral Liquid-II	23	10
Oral Dry Powder-II	20	10

Oral Liquid-I
(30 Products/ 10 Molecules)

466.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Mectiver Plus Oral Drench

	Composition	Each ml contains: Ivermectin…0.8mg
	Diary No. Date of R& I & fee	Dy.No 6854 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Ivotek Drench of M/s Star Labs Lahore (Reg. No. 026541)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
467.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Mectiver Oral Drench
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 6853 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Ivotek Drench of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 062141)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
468.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Mectiver Super Oral Drench
	Composition	Each ml contains: Ivermectin…0.24%
	Diary No. Date of R& I & fee	Dy. No 6855 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Elvomec Drench 0.24% of M/s Elko Organization (Pvt) Ltd., Karachi. (Reg. No. 063730)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
469.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fexazol Plus Oral Drench

	Composition	Each ml contains: Oxfendazole…25mg Cobalt Sulphate…2mg Sodium Selenite…0.5mg
	Diary No. Date of R& I & fee	Dy.No 6849 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ Antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision:Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
470.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fexazol SC Oral Drench
	Composition	Each ml contains: Oxfendazole…22.65mg Cobalt Sulphate…3.82mg Sodium Selenite…0.35mg
	Diary No. Date of R& I & fee	Dy.No 6848 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ Antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Oxfendacon Plus Drench of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir (Reg. No. 057194)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
471.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmelev DS Oral Suspension
	Composition	Each ml contains: Oxyclozanide…0.3mg Levamisole HCl…0.15mg Sodium Selenite…0.038mg Cobalt Chloride…0.035mg
	Diary No. Date of R& I & fee	Dy.No 6861 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications

	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
472.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmelev Forte Oral Suspension
	Composition	Each ml contains: Oxyclozanide…30mg Levamisole HCl…15mg Sodium Selenite…7.5mg Cobalt Chloride…3.82mg
	Diary No. Date of R& I & fee	Dy.No 6860 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Roldzen Suspension of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109066)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
473.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmelev Gold Oral Suspension
	Composition	Each ml contains: Oxyclozanide…60mg Levamisole HCl…30mg Sodium Selenite…0.76mg Cobalt Chloride…7.64mg
	Diary No. Date of R& I & fee	Dy.No 6859 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Levofas Gold Oral Suspension of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 048159)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	

474.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmelev SC Oral Suspension
	Composition	Each ml contains: Oxyclozanide…60mg Levamisole HCl…30mg Sodium Selenite…0.7mg Cobalt Chloride…1.5mg
	Diary No. Date of R& I & fee	Dy.No 6858 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Roldzen Super Suspension of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No.109067)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
475.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmelev Plus Oral Suspension
	Composition	Each ml contains: Oxyclozanide…30mg Levamisole HCl…15mg Sodium Selenite…0.5mg Cobalt Chloride…1.67mg
	Diary No. Date of R& I & fee	Dy.No 6857 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Roldzen PL Oral Suspension of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No.109065)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
476.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmelev Oral Suspension
	Composition	Each ml contains: Oxyclozanide…30mg Levamisole HCl…15mg Sodium Selenite…0.35mg Cobalt Chloride…0.75mg

	Diary No. Date of R& I & fee	Dy.No 6856 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Nilzole Liquid of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No.034545)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
477.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acetil Oral Liquid
	Composition	Each ml contains: Tilmicosin…250mg
	Diary No. Date of R& I & fee	Dy.No 6844 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Tilmic Oral Solution of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No. 063809)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
478.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ofloxa-10 Oral Liquid
	Composition	Each ml contains: Ofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 6877 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Oflobak Liquid of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063829)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
479.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad

	Brand Name +Dosage Form + Strength	Acmeflor-20 Oral Liquid
	Composition	Each ml contains: Florfenicol…200mg
	Diary No. Date of R& I & fee	Dy.No 6867 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	I-Enicol Solution of M/s International Pharma Labs, Lahore. (Reg. No. 112298)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
480.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflor-10 Oral Liquid
	Composition	Each ml contains: Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 6868 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Maxi-Flor Liquid of M/s Biogen Pharma, Rawat. (Reg. No. 075612)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
481.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflor-23 Oral Liquid
	Composition	Each ml contains: Florfenicol…230mg
	Diary No. Date of R& I & fee	Dy.No 6869 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Neflox Solution of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049647)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	

482.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflor-25 Oral Liquid
	Composition	Each ml contains: Florfenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 6870 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Florfenicol Oral Liquid of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 075707)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
483.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Cobraflox Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…0.5 MIU Bromhexine HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 6846 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic/ **benzylamine**
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Inter Flox Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 078241)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
484.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 20/20 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…20% Colistin Sulphate…0.2 MIU
	Diary No. Date of R& I & fee	Dy.No 6893 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	EC Skill-40 Liquid of M/s Bioskils Pharmaceuticals, Sadhoke, District Gujranwala (Reg. No. 111255)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
485.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 10/50 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…5,00,00 IU
	Diary No. Date of R& I & fee	Dy.No 6892 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
486.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 20/3 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…20% Colistin Sulphate…3%
	Diary No. Date of R& I & fee	Dy.No 6891 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Enrosir-20 Oral Liquid of M/s Attabak Pharmaceutical Islamabad (Reg. No. 071060)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
487.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad

	Brand Name +Dosage Form + Strength	Acmecoliflox 25/50 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…250mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6890 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Vitaflox-C 25% Oral Liquid of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No.079276)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
488.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 10/48 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…0.48 MIU
	Diary No. Date of R& I & fee	Dy.No 6894 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
489.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 20/50 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…200mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6895 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled

	Me-too status	Floxicol Oral Liquid of M/s Biogen Pharma Rawat (Reg. No. 058966)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
490.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmicoliflox 10/52 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…0.52 MIU
	Diary No. Date of R& I & fee	Dy.No 6896 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bioenrocolis Liquid of M/s Elegance Pharmaceutical, Chak Belli, Rawalpindi (Reg. No. 073916)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
491.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecol-44 Oral Liquid
	Composition	Each ml contains: Colistin Sulphate…4.8 MIU
	Diary No. Date of R& I & fee	Dy.No 6886 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Colostine Oral Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 078360)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
492.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecol-20 Oral Liquid
	Composition	Each ml contains: Colistin Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 6885 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications

	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Avi-Col Oral Liquid of M/s Avicenna Laboratories (Pvt) Ltd., Sheikhupura (Reg. No. 071049)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
493.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflox-25 Oral Liquid
	Composition	Each ml Contains: Enrofloxacin…0.25mg
	Diary No. Date of R& I & fee	Dy.No 6889 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
494.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflox-20 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 6888 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Enronoor Fort Oral Liquid of M/s Kohinoor Industries, Sahiwal (Reg. No. 081315)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
495.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflox-10 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg

	Diary No. Date of R& I & fee	Dy.No 6887 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Enrosym Oral Solution of M/s Symans Lahore (Reg. No. 022748)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
Oral Liquid-II (23 Products/ 10 Molecules)		
496.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-11 Oral Liquid
	Composition	Each ml contains: Florfenicol…110mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6864 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Florfarm Liquid of M/s Farm Aid Group, Haripur (Reg. No. 097997)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
497.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-2.5 Oral Liquid
	Composition	Each ml contains: Florfenicol…100mg Colistin Sulphate…25mg
	Diary No. Date of R& I & fee	Dy.No 6863 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Co-Flor Liquid of M/s Wimits Pharmaceuticals, Lahore (Reg. No. 078326)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	

498.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-25 Oral Liquid
	Composition	Each ml contains: Florfenicol…250mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6862 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Tye-Fol Liquid of M/s Farm Aid Group, Haripur (Reg. No. 092176)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
499.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-10 Oral Liquid
	Composition	Each ml contains: Florfenicol…100mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6865 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Florobex-C Liquid of M/s Elegance Pharmaceuticals, Chak Belli,Rawalpindi.(Reg. No. 078286)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
500.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-23 Oral Liquid
	Composition	Each ml contains: Florfenicol…230mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6866 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**

	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
501.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Sulflox Plus Oral Liquid
	Composition	Each ml contains: **Enrofloxacin**…75mg **Sulphamethoxypyridazine**…50mg **Sulphamethazine**…50mg **Trimethoprim**…25mg
	Diary No. Date of R& I & fee	Dy.No 6876 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074786)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
502.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Sulflox DS Oral Liquid
	Composition	Each ml contains: **Enrofloxacin**…75mg **Sulphamethoxypyridazine**…75mg **Sulphamethazine**…50mg **Trimethoprim**…25mg
	Diary No. Date of R& I & fee	Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No.031456)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
503.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad

	Brand Name +Dosage Form + Strength	Bromithol Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…10mg Menthol…20mg
	Diary No. Date of R& I & fee	Dy.No 6874 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bromotin Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No.073999)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
504.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Bromithol Plus Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…20mg Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 6873 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bromo-Plus Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 073917)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
505.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Broxine-10 Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 6872 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:**

		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
506.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Broxine-5 Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 6871 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bromit 5% Oral Solution of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 112386)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
507.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	AG-Flox DS Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Aminophylline…100mg Guaiphenesin…40mg
	Diary No. Date of R& I & fee	Dy.No 6884 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Ensol-AG Oral Liquid of M/s Biogen Pharma, Rawat (Reg. No. 049720)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
508.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	AG-Flox Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Aminophylline…40mg Guaiphenesin…100mg

	Diary No. Date of R& I & fee	Dy.No 6883 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Enrophylin Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080730)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
509.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmadek Gold Oral Liquid
	Composition	Each ml contains: Vitamin E (alpha tocopheryl acetate) …15mg Vitamin A (retinol oily form) …2,500 IU Vitamin K3 (Menadione) …2.5mg Vitamin D3 (calcifediol) …250 MIU
	Diary No. Date of R& I & fee	Dy.No 6882 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
510.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmadek Oral Liquid
	Composition	Each ml contains: Vitamin E (alpha tocopheryl acetate) …5mg Vitamin A (retinol oily form) …0.03 MIU Vitamin K3 (Menadione) …0.600mg Vitamin D3 (calcifediol) …0.001 MIU
	Diary No. Date of R& I & fee	Dy.No 6881 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML

	Remarks of the Evaluator [X]	**Shortcomings:** • Clarification regarding applied strength since Vitamin E.....5000mg/1000ml is mentioned on cover letter while Vitamin E.....600mg/1000ml is mentioned in label claim on Form-5. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
511.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmadek Super Oral Liquid
	Composition	Each ml contains: Vitamin E (alpha tocopheryl acetate) …4mg Vitamin A (retinol oily form) …10,000 IU Vitamin K3 (Menadione) …2mg Vitamin D3 (calcifediol) …2,000 IU
	Diary No. Date of R& I & fee	Dy.No 6880 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Symodex Oral Liquid of M/s Biogen Pharma, Rawat. (Reg. No. 080144)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
512.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Bendol Plus 3% Oral Suspension
	Composition	Each ml contains: Albendazole…3% Cobalt Chloride…0.050% Sodium Selenite…0.030%
	Diary No. Date of R& I & fee	Dy.No 6879 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bendzole 3% Suspension of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063819)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
513.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad

	Brand Name +Dosage Form + Strength	Bendol Plus 2.5% Oral Suspension
	Composition	Each ml contains: Albendazole…25mg Cobalt Chloride…0.75mg Sodium Selenite…0.35mg
	Diary No. Date of R& I & fee	Dy.No 6878 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Soletin Oral Suspension of M/s Aamster Laboratories, Islamabad (Reg. No. 101436)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
514.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmefenda Plus Oral Drench
	Composition	Each ml contains: Oxyclozanide…94mg Oxfendazole…34mg Cobalt Sulphate…3.82mg Sodium Selenite…0.5mg
	Diary No. Date of R& I & fee	Dy.No 6852 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Combiox Drench of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 057004)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
515.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmefenda Super Oral Drench
	Composition	Each ml contains: Oxyclozanide…62.50gm Oxfendazole…25mg Cobalt Sulphate…2mg Sodium Selenite…0.5mg
	Diary No. Date of R& I & fee	Dy.No 6851 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled

	Me-too status	Nidozole Drench of M/s Haarolds Pharmaceuticals (Pvt) Ltd Bhimber, AJK (Reg. No. 109084)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
516.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmefenda Oral Drench
	Composition	Each ml contains: Oxyclozanide…62.50gm Oxfendazole…22.65mg Cobalt Sulphate…1.67mg Sodium Selenite…0.5mg
	Diary No. Date of R& I & fee	Dy.No 6850 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Cloxa Gold Drench of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 046669)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
517.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Aceoxol Oral Liquid
	Composition	Each ml contains: Oxolinic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 6847 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Vety Oxol Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 046668)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
518.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Peflo-10 Oral Liquid
	Composition	Each ml contains: Pefloxacin Methanse Sulfonate Eq. to Pefloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 6845 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	PEF-Rold Oral Liquid of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109062)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
Oral Dry Powder-II (20 products/ 10 Molecules)		
519.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acme-Flush WSP
	Composition	Each gram contains: Furosemide…20mg Sodium Chloride…35mg Potassium Chloride…4mg Calcium Carbonate…45mg Magnesium Sulphate…35mg Manganese Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 6820 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Vitamin/Diuretic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Farsolyte Oral Powder of M/s Farm Aid Group, Hattar. (Reg. No. 044999)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021
	Decision: Approved. The firm shall submit the Fee of Rs. 30,000/- for correction in formulation (salt form of Furosemide) and pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
520.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acme NOC Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…200mg Neomycin Sulphate…200mg Colistin Sulphate…0.24 MIU
	Diary No. Date of R& I & fee	Dy.No 6804 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled

	Me-too status	Stiagulstin 24 Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109134)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
521.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acme NOC Forte Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…250mg Neomycin Sulphate…250mg Colistin Sulphate…0.3MIU
	Diary No. Date of R& I & fee	Dy.No 6805 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Oxycol Forte Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 071068)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
522.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acme NOC 20/20 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…200mg Neomycin Sulphate…200mg Colistin Sulphate…0.55 MIU
	Diary No. Date of R& I & fee	Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg,: Decontrolled
	Me-too status	Stiagulstin 55 Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109137)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
523.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Apra-C Oral Powder
	Composition	Each gram contains: Vitamin C…200mg **Paracetamol**…20mg

		Potassium Chloride…40mg Calcium Carbonate…450mg Magnesium Sulphate…35mg
	Diary No. Date of R& I & fee	Dy.No 6798 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Vitamin/ NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Paravit-C Water Soluble Powder of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 074081)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
524.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acme NOC Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…300mg Neomycin Sulphate…250mg Colistin Sulphate…0.5 MIU
	Diary No. Date of R& I & fee	Dy.No 6823 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Oxyneoriq-C Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073952)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
525.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmepro-50 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 6799 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-protozoal/ Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Pentaprol 50 Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Kamoke (Reg. No.111414)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	

526.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmentadin 10% Water Soluble Powder
	Composition	Each gram contains: **Amantadine HCl**…100mg
	Diary No. Date of R& I & fee	Dy.No 6824 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Amancin-10 Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi (Reg. No. 112234)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
527.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmentadin 98% Water Soluble Powder
	Composition	Each gram contains: **Amantadine HCl**…0.980gm
	Diary No. Date of R& I & fee	Dy.No 6825 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 094402)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
528.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florotet 15/15 Oral Powder
	Composition	Each gram contains: Oxytetracycline HCl…150mg Florfenicol…150mg
	Diary No. Date of R& I & fee	Dy.No 6828 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Ox-Keyan 30 Water Soluble Powder of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 111379)
	GMP status	New DML

	Remarks of the Evaluator [X]	
	Decision: Approved.	
529.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florotet 30/30 Oral Powder
	Composition	Each gram contains: Oxytetracycline HCl…300mg Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 6829 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Ox-Keyan 60 Water Soluble Powder of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 111380)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
530.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmepro-90 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl…900mg
	Diary No. Date of R& I & fee	Dy.No 6834 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-protozoal/ Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Mak Amprolium Powder of M/s Medicure Laboratories, Karachi. (Reg. No.063609)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
531.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmetet-N 2.5 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…250mg Neomycin Sulphate…150mg
	Diary No. Date of R& I & fee	Dy.No 6841 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML

	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
532.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmetet-N 10 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…100mg Neomycin Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 6842 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
533.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmetet-N 1.5 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…15mg Neomycin Sulphate…15mg
	Diary No. Date of R& I & fee	Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

534.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmetet-N 2.2 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…22.22mg Neomycin Sulphate…22.22mg
	Diary No. Date of R& I & fee	Dy.No 6839 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Nexybak Water Soluble Powder of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 063840)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
535.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmetet-N 5 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…50mg Neomycin Sulphate…50mg
	Diary No. Date of R& I & fee	Dy.No 6840 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Oxy-N-50 Powder of M/s Symans Pharmaceuticals Lahore (Reg. No. 013685)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
536.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florotet-N Forte Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…3mg Neomycin Sulphate…1.5mg Florfenicol…1mg
	Diary No. Date of R& I & fee	Dy.No 6830 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled

	Me-too status	Eter Neo Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113452)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
537.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Virgocine Water Soluble Powder
	Composition	Each gram contains: Vitamin E…5mg Vitamin B3…2mg L Lysine…25mg DL Methionine…50mg Choline Chloride…100mg Virginiamycin…12mg
	Diary No. Date of R& I & fee	Dy.No 6802 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Multivitamins/Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Maji Max Oral Water Soluble Powder of M/s Majestic Pharma, Faisalabad. (Reg. No. 089848)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
538.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dairy Booster Water Soluble Powder
	Composition	Each gram contains: Vitamin A…0.8mg Vitamin D3…0.16mg Vitamin E...0.38mg Vitamin B1...1mg Vitamin B2...1.25mg Vitamin B12...0.001mg Vitamin B3...6.25mg Copper Sulphate...0.25mg Magnesium Sulphate...25mg Calcium Chloride...0.023mg Manganese Sulphate...10mg Potassium Iodide...0.5mg Sodium Selenite...0.01mg DCP...150mg Sodium Chloride...120mg Vitamin B6...4mg Zinc Sulphate...2.17mg
	Diary No. Date of R& I & fee	Dy.No 6822 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Multivitamins & Minerals
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled

	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad. (Reg. No. 058842)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	

Case No. 1: Registration applications of Human Drugs on form 5F (New DML):

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.

539.	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)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 22-11-2022 based on inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13/09/2021. Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	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. 1371 dated 16/01/2023
	Details of fee submitted	PKR 30,000/-: dated 06/01/2023 (Deposit slip#70103647320)
	The proposed proprietary name / brand name	Neptune 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin……500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciproxin 500mg film-coated Tablets, MHRA Approved.
	For generic drugs (me-too status)	Ciproxin 500mg Tablet by M/s Bayer Pakistan Private Limited (Reg#107222)
	Name and address of API manufacturer.	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km Ferozpur 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 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 verifications, batch analysis and justification of specification details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data as per zone IV-A. Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: 00510011/001/2014, 00510011/002/2014, 00510011/003/2014
	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 submitted results of pharmaceutical equivalence for their product against ciproxin 500mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) by performing quality tests (Identification, average weight, disintegration time, uniformity of dosage units, dissolution, assay) CDP has been performed against the product ciproxin 500mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) 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 Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore		
API Lot No.	00510011 / 279 / 2021		
Description of Pack (Container closure system)	Alu-Alu blister packed in 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, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T047	T054	T055
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	16-05-2022	18-05-2022	18-05-2022
Date of Initiation	01-06-2020	01-06-2020	01-06-2020
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 has submitted copy of GMP Certificate of M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore issued on 22-11-2022 based on inspection conducted on 18-11-2022 valid for two years from date of inspection
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 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)	Not Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
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>	
3.2.S.4	• Clarification is required as Drug substance manufacturer has given both USP and BP specifications and analytical method while drug product manufacturer has given USP specifications. • Clarification is required as the batch number mentioned on COA of drug substance by drug substance manufacturer (00510011 / 279 / 2021) is different than that of drug product manufacturer (00510011 / 280 / 2021)	
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.5	• Justification is required for not mentioning the time for dissolution test in finished product specifications as recommended by USP.	
3.2.P.8	• Documents for the procurement of API is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	

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

540.	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)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 22-11-2022 based on inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13/09/2021. Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	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. 1370 dated 16/01/2023
	Details of fee submitted	PKR 30,000/-: dated 06/01/2023 (Deposit slip#100252509767)
	The proposed proprietary name / brand name	Neptune 250mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin……250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO (250mg) film coated tablet, USFDA Approved.
	For generic drugs (me-too status)	Ciproxin 250mg Tablet by M/s Bayer Pakistan Private Limited (Reg# 10118)
	Name and address of API manufacturer.	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km Ferozpur 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, 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 verifications, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data as per zone IV-A. Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: 00510011/001/2014, 00510011/002/2014, 00510011/003/2014
	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 submitted results of pharmaceutical equivalence for their product against ciproxin 250mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) by performing quality tests (Identification, average weight, disintegration time

		uniformity of dosage units, dissolution, assay) CDP has been performed against the product ciproxin 250mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) 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 Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore		
API Lot No.	00510011 / 279 / 2021		
Description of Pack (Container closure system)	Alu-Alu blister packed in 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, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T049	T051	T052
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	12-05-2022	16-05-2022	16-05-2022
Date of Initiation	01-06-2020	01-06-2020	01-06-2020
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 has submitted copy of GMP Certificate of M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore issued on 22-11-2022 based on inspection conducted on 18-11-2022 valid for two years from date of inspection
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 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)	Not Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response

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>	
3.2.S.4	• Clarification is required as Drug substance manufacturer has given both USP and BP specifications and analytical method while drug product manufacturer has given USP specifications. • Clarification is required as the batch number mentioned on COA of drug substance by drug substance manufacturer (00510011 / 279 / 2021) is different than that of drug product manufacturer (00510011 / 280 / 2021)	
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.5	• Justification is required for not mentioning the time for dissolution test in finished product specifications as recommended by USP.	
3.2.P.8	• The batch number mentioned on chromatograms for assay test at 3rd month time point of real time and accelerated stability study is T047 instead of T049 clarify • In real time stability study at 3rd month and 6th month time point of batch#T052, chromatograms of Batch#T051 is submitted instead of Batch#T052, clarify • Documents for the procurement of API is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	

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

Case No. 2: Registration applications of Human Drugs on form 5F (New Section):
M/s Bio Labs Pvt. Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad has applied for registration of the following products in new section / new license:

541.	M/s Bio Labs Pvt. Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad has applied for registration of the following products in new section of "Dry Vial Injection (General)": **Vancozek 1g Injection** Each vial contains: Vancomycin HCL for injection eq. to vancomycin ……1g Type of form: Form-5F Dy. No. 34295 dated 28-11-2022 PKR 30,000/-: dated 22-09-2022 (Deposit slip#500444816716) **Remarks:** The applicant, M/s Bio Labs Pvt. Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad is already granted with the above mentioned formulations with the following details; **Vancocin 1000mg Vial** Each vial contains: Vancomycin HCl for injection eq. to vancomycin……1g (USP Specs) Registration number: 075191 *The registrations of the above mentioned products were granted vide letter No.F.8-6/2012-Reg.III(M-236) dated 08th February, 2013. The case is hereby placed before the Board.
Decision: Registration Board was apprised that the applicant already hold registration of the above mentioned finished products. The Board discussed that the new applied products contain same formulation as that of already registered products thus the Board decided to reject the applications for Vancozek (Vancomycin HCl) 1g Injection.	

Case No. 3: Registration applications of Human Drugs on form 5F (New DML):

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.

542.	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)
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	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. 3117; dated 02/02/2023
	Details of fee submitted	PKR 30,000/-: dated 24/01/2023 (Deposit slip#16971617094)
	The proposed proprietary name / brand name	Krasil Injection 500mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml vial contains: Amikacin as sulphate BP……..500mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotics
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Amikacin 250mg/ml Injection (500mg/2ml vial), by M/s Hospira UK Limited MHRA approved
	For generic drugs (me-too status)	Zomacin Injection 250mg by M/s Standpharm Pakistan (Reg#23515)

	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co. Ltd., No. 849, Dongjia Town, Licheng District, Jinan, 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 for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (120835205A, 120835505A, 120835805A)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, 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 submitted results of pharmaceutical equivalence for their product against Amikacin by M/s Hospira UK Limited by performing quality tests (Description, acidity, particulate matter, assay, sterility test, bacterial endotoxin)
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong Anxin Pharmaceutical Co. Ltd., No. 849, Dongjia Town, Licheng District, Jinan, China		
API Lot No.	**RA 2014A**		
Description of Pack (Container closure system)	Clear Glass ampoule type-I, 2mlx1'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.	KS/I-T01	KS/I-T02	KS/I-T03
Batch Size	1000 ampoule	1000 ampoule	1000 ampoule

Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	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)	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).	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, for initial time point only and stability summary sheet for six months
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
	• Submit module 1 of form 5F as many sections are marked unattended	•
1.6.5	Submit valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	•
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>	•
3.2.S.4	• Justification is required for not including test for sulphate in drug substance specifications by drug substance manufacturer as recommended by BP • Justification is required for selecting different chromatographic conditions (mobile phase composition, wavelength, column oven temperature, run time) by drug product manufacturer for drug substance than that recommended by drug substance manufacturer and BP • 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 as whether the drug substance follow BP specifications or USP specifications as both are mentioned on COA provided by drug substance manufacturer in batch analysis	•
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.1	• Justifications is required for using sulfuric acid for pH adjustment as the reference product does not use this for pH adjustment	•
3.2.P.2	• Submit the details of brand name, batch No# and expiry date of innovator/reference/comparator product against which pharmaceutical equivalence profile studies have been performed • Justification is required for not performing the pH test for applied product in pharmaceutical equivalence.	•

	• Justification is required since pharmaceutical equivalence studies have not been conducted against the innovator product. • Label claim for applied product mentioned in module 1 of form 5F is vial while primary packaging material is ampoule, clarify	
3.2.P.7	• Applied product is packed in ampoule while reference product is packed in vials, clarify	•
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP • Chromatograms, Raw data sheets and COA stability study at 3rd month and 6th month time point not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	•

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

Case No. 4: Registration applications of Human Drugs on form 5F (New DML):

M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.

The Central Licensing Board in its 282nd meeting held on 31st August, 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following seven (07) sections to M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot under Drug Manufacturing License No. 000944 vide approval letter No. F.1-5/2017-Lic dated 17/09/2021. The Drug Manufacturing License No. 000944 by way of formulation is hereby issued w.e.f. 13-09-2021.

S No.	Section
1.	Tablet (General)
2.	Capsule (General)
3.	Oral Liquid (General)
4.	Liquid Injectable – Vial & Ampoule (General)
5.	Capsule (Cephalosporin)
6.	Dry Powder Injectable (Cephalosporin)
7.	Oral Dry Powder Suspension (Cephalosporin)

Following applications have been submitted for registration by the firm.

543.	Name, address of Applicant / Mar keting Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000944) by way of formulation dated 17-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies Capsule (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. 3131 : 02/02/2023

	Details of fee submitted	PKR 30,000/-: 12/12/2022 (Deposit slip#7485549404)
	The proposed proprietary name / brand name	Praq 20mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatine capsule contains: Enteric coated pellets (8.5%) of omeprazole equivalent to omeprazole …….20mg
	Pharmaceutical form of applied drug	Hard gelatine capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 20 mg Gastro-resistant Capsules MHRA Approved
	For generic drugs (me-too status)	Risek Capsule 20mg by M/s Getz Pharma (Reg#19364)
	Name and address of API manufacturer.	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. Firm has 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.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (OMP073,)
	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 results of pharmaceutical equivalence for their product against Risek 20mg capsule by performing quality tests (appearance, identification, dissolution, assay)

	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, linearity, range, accuracy, precision (repeatability), system suitability.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	OMP1199		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 2x7'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.	T001	T002	T003
Batch Size	658 capsule	658 capsule	658 capsule
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	27-04-2022	27-04-2022	27-04-2022
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)	No reference is submitted by 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 cGMP certificate of M/s Vision Pharmaceuticals issued on 22-08-2022 based on inspection conducted on 14-06-2022.
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.	Firms 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)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
2.3.R.1	• Justification is required for using 2% overage in finished product as mentioned in BMR • Justification shall be submitted for the dispensed quantity of Omeprazole pellets against the label claim with reference to the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma.	•

3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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. • Justification shall be submitted for incomplete testing of drug substance by drug product manufacturer as recommended by drug substance manufacturer (loss on drying, sugar test, pellet size, bulk density). • Clarification shall be submitted regarding declared the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma whether it is on "as is basis" or "anhydrous basis".	•
3.2.S.7	• Stability study of at least three batches of drug substance till claimed shelf life shall be submitted	•
3.2.P.2	• Submit the details of manufacturer, batch No# and expiry date of innovator/reference/comparator product against which pharmaceutical equivalence studies have been performed • 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 (uniformity of dosage units). • Justification is required since pharmaceutical equivalence have not been conducted against the innovator product. • Submit CDP studies of applied product as per guidelines approved by the registration board in its 293rd meeting	•
3.2.P.5	• Justification is required for not including the test for uniformity of dosage units in finished product specifications as recommended by USP. • Justification is required for not mentioning the test number and time for dissolution test in finished product specifications at buffer stage as recommended by USP. • Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is required from M.s Qadir Pharmaceuticals instead of referring to the USP monograph extract.	•
3.2.P.8	• The batch number of manufactured batches mentioned in BMR is CTR001, CTR002, CTR003 while batch number mentioned stability summary sheet is T001, T002, T003, clarify • Justification is required since results of dissolution test in stability summary sheets at acid stage of batch No#T001 Accelerated conditions at 6th month time point, T002 Accelerated conditions at 6th month time point, T003 real time conditions at 3rd and 6th month time point show results in terms of negative percentage. • Justification shall be submitted for performing the dissolution test at acid stage on HPLC and at buffer stage on UV spectrophotometer in stability studies • Clarification shall be submitted regarding the calculation formula applied for the results of Acid stage dissolution test with reference to the USP monograph since firm has represented the dissolution results as more than 90% in raw data sheets of acid stage dissolution test and has further subtracted results of dissolution test at acid stage from assay test for calculating final results. • Submit document for procurement of API.	•

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

544.	Name, address of Applicant / Mar keting Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.

	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000944) by way of formulation dated 17-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies Capsule (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. 5904 : 02/03/2023
	Details of fee submitted	PKR 30,000/-: 07/12/2022 (Deposit slip#556684006746)
	The proposed proprietary name / brand name	Praq 40mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatine capsule contains: Enteric coated pellets (22.5%) of omeprazole equivalent to omeprazole …….40mg
	Pharmaceutical form of applied drug	Hard gelatine capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	2x7’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg gastro-resistant capsules MHRA Approved
	For generic drugs (me-too status)	Risek Capsule 40mg by M/s Getz Pharma (Reg#22109)
	Name and address of API manufacturer.	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. Firm has 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.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (OMP065, OMP103, OMP083)
	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 results of pharmaceutical equivalence for their product against Risek 40mg capsule by performing quality tests (appearance, identification, dissolution, assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, linearity, range, accuracy, precision (repeatability), system suitability.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	OMP896		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 2x7'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.	T001	T002	T003
Batch Size	658 capsule	658 capsule	658 capsule
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	03-05-2022	04-05-2022	04-05-2022
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)	No reference is submitted by 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 cGMP certificate of M/s Vision Pharmaceuticals issued on 22-08-2022 based on inspection conducted on 14-06-2022.
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.	Firms 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 submitted that our system is not 21 CFR compliant and audit trail reports on product testing is not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
2.3.R.1	• Justification is required for using 1.25% overage in finished product as mentioned in BMR • Justification shall be submitted for the dispensed quantity of Omeprazole pellets against the label claim with reference to the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma.	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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. • Justification shall be submitted for incomplete testing of drug substance by drug product manufacturer as recommended by drug substance manufacturer (loss on drying, sugar test, pellet size, bulk density). • Clarification shall be submitted regarding declared the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma whether it is on "as is basis" or "anhydrous basis".	•
3.2.P.2	• Submit the details of manufacturer, batch No# and expiry date of innovator/reference/comparator product against which pharmaceutical equivalence studies have been performed • 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 (uniformity of dosage units). • Justification is required since pharmaceutical equivalence have not been conducted against the innovator product. • Submit CDP studies of applied product as per guidelines approved by the registration board in its 293rd meeting	•
3.2.P.5	• Justification is required for not including the test for uniformity of dosage units in finished product specifications as recommended by USP. • Justification is required for not mentioning the test number and time for dissolution test in finished product specifications at buffer stage as recommended by USP. • Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is required from M.s Qadir Pharmaceuticals instead of referring to the USP monograph extract.	•
3.2.P.8	• The batch number of manufactured batches mentioned in BMR is CTR001, CTR002, CTR003 while batch number mentioned stability summary sheet is T001, T002, T003, clarify • Justification is required since results of dissolution test in stability summary sheets at acid stage of batch No#T003 Accelerated conditions at 3rd month time point show results in terms of negative percentage. • Justification shall be submitted for performing the dissolution test at acid stage on HPLC and at buffer stage on UV spectrophotometer in stability studies • Clarification shall be submitted regarding the calculation formula applied for the results of Acid stage dissolution test with reference to the USP monograph since firm has represented the dissolution results as more than	•

	90% in raw data sheets of acid stage dissolution test and has further subtracted results of dissolution test at acid stage from assay test for calculating final results. • Submit document for procurement of API.	

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

Agenda of Evaluator PEC-XIII

539.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, 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. 3116; dated 02/02/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.6901084368 dated 01/08/2022.
	The proposed proprietary name / brand name	Invipam 500mg Injection IM/IV.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine ……..…….500mg
	Pharmaceutical form of applied drug	Sterile Powder for injection.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1’s.
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	MAXIPIME 500mg & 1gm (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 500mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 030953.
	GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.

	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, 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)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (11C0742107001, Mfg. date 12-07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. 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: (11C0741702001, 11C0741702002 & 11C0741702003)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, 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 brand leader that is Maxipime 500mg IV/IM injection batch No. Y83J, mfg. date 01-2021 manufactured by GSK, Pakistan by performing quality tests (Identification, water content, pH, bacterial endotoxin, sterility & Assay).
	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 Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China.
API Lot No.	Not provided.
Description of Pack (Container closure system)	Transparent Type II glass vial filled with powder, closed with rubber stopper and flip-off seal.
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.	TDI001	TDI002	TCH001
Batch Size			
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
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)	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 manufacturing license No. Lu 20150511 valid till 26-10-2025. (Raw materials, Sterile raw materials)
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 Submitted
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	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are	

		different from the specification of the drug substance in the stability data sheets. Justification shall be submitted. • Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	
8.	3.2.P.5.1	Specifications provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Clarification shall be submitted.	
9.	3.2.P.5.2	Analytical procedures provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Signed analytical procedures for the drug product shall be submitted.	
10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

540.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, 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. 1853; dated 19/01/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.0829772894 dated 01/08/2022.
	The proposed proprietary name / brand name	Invipam 1000mg Injection IM/IV.

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine ……..…….1000mg
	Pharmaceutical form of applied drug	Sterile Powder for injection.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	MAXIPIME 500mg, 1gm & 2gm (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 1000mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 030954.
	GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, 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)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (11C0742107001, Mfg. date 12-07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. 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: (11C0741702001, 11C0741702002 & 11C0741702003)

	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, 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 brand leader that is Maxipime 1000mg IV/IM injection batch No. Y83J, mfg. date 01-2021 manufactured by GSK, Pakistan by performing quality tests (Identification, water content, pH, sterility, bacterial endotoxin & Assay).
	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 Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Transparent Type II glass vial filled with powder, closed with rubber stopper and flip-off seal.		
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.	TDI001	TDI002	TCH001
Batch Size			
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
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)	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 manufacturing license No. Lu 20150511 valid till 26-10-2025. (Raw materials, Sterile raw materials)
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 Submitted
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	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are different from the specification of the drug substance in the stability data sheets. Justification shall be submitted. • Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	
8.	3.2.P.5.1	Specifications provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Clarification shall be submitted.	
9.	3.2.P.5.2	Analytical procedures provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Signed analytical procedures for the drug product shall be submitted.	
10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. • Documents for the procurement of API with approval from DRAP shall be submitted.	

		• Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

541.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, 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. 2384; dated 25/01/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.91779456 dated 04/08/2022.
	The proposed proprietary name / brand name	Invipam 2000mg Injection IM/IV.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine ……..…….2000mg
	Pharmaceutical form of applied drug	Sterile Powder for injection.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	MAXIPIME 500mg, 1gm & 2gm (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 2000mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 089284.
	GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, 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)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (11C0742107001, Mfg. date 12-07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. 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: (11C0741702001, 11C0741702002 & 11C0741702003)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, 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 brand leader that is Maxum 2000mg injection batch No. 218006, mfg. date 02-2021 manufactured by M/s Highnoon pharma by performing quality tests (Identification, water content, pH, sterility, bacterial endotoxin & Assay).
	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 Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Transparent Type II glass vial filled with powder, closed with rubber stopper and flip-off seal.		
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.	TDI001	TDI002	TCH001
Batch Size			

Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
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)	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 manufacturing license No. Lu 20150511 valid till 26-10-2025. (Raw materials, Sterile raw materials)
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 Submitted
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	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are different from the specification of the drug substance in the stability data sheets. Justification shall be submitted. • Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on	

		anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	
8.	3.2.P.2.2	Justification shall be submitted for not performing PE against the innovator product.	
9.	3.2.P.5.2	Signed analytical procedures for the drug product shall be submitted.	
10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

Agenda of Evaluator PEC-XV

548.	Central Licensing Board in 272nd meeting held on 17th October,2019 has considered and approved additional section "Tablet II (General section)" of M/s Don Valley Pharmaceuticals Private Limited.	
	Name, address of Applicant / Marketing Authorization Holder	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals Private Limited 31km Main 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. -dated: 9th March 2023
	Details of fee submitted	PKR 30,000/-: dated 09/02/2023
	The proposed proprietary name / brand name	Ocalidon 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid…….5mg
	Pharmaceutical form of applied drug	Yellow colored, Round biconvex shaped, without any score, Film coated oral tablet
	Pharmacotherapeutic Group of (API)	Farnesoid X receptor agonists
	Reference to Finished product	In-house

	specifications	
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ocaliva 5mg tablet by M/s Intercept Pharma Limited EMA Approved.
	For generic drugs (me-too status)	Abeticholic 5mg Tablet by M/s Dyson Research Laboratories Pvt. Ltd., Reg. No. 109521
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on dated 06-08-2019. Section approval letter issued on 05.11.2019
	Name and address of API manufacturer.	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu 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 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: (20171001, 20171101, 20171102)
	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 product that is Ocaliva 5mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ocaliva 5mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) 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 validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province China.
API Lot No.	**20220802**
Description of Pack	Alu-Alu blister packed in unit carton (3×10's)

(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: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3(Months) Real Time: 0, 3(Months)		
Batch No.	KB-22-001	KB-22-002	KB-22-003
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	28-10-2022	28-10-2022	28-10-2022
No. of Batches	03		

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Gutain 30 mg and Gutain 60 mg capsule approved in 324 DRB Meeting
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. JS20191190 issued by Jiangsu Drug Administration valid till 29/11/2024.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No. **K-1107632926281** dated 13/10/2022 is submitted wherein the permission to import different APIs including Obeticholic Acid for the purpose of test/analysis and stability studies is granted. • Invoice No. 22YX0049L dated 15/09/2022
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:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2. S.4.1**	Justify for not including the test of parcticle size distribution, palladium test and solid state form test in the specification of drug substance by drug substance manufacturer, since these tests are included in the specification of drug substance of innovator product.
2.	**3.2.S.4.1-3.2.S.4.2**	• Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer 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". Since you have only submitted the specification and analytical procedure by drug substance manufacturer. • Submit detailed analytical procedure of drug substance by drug substance manufacturer, since the submitted procedure seems incomplete or only refer the general chapters of USP.
3.	**3.2.S.4.3**	• Justify for performing validation study of assay procedure which is different from the assay method by drug substance manufacturer given in section 3.2.S.4.2.

		• Further drug substance manufacturer used RID detector in the HPLC system for assay while the submitted chromatogram of validation studies reflect that the assay has performed by setting the wavelength of detector at 210nm, Justify for using the different detector from that specified by drug substance manufacturer.
4.	**3.2.S.5**	COA of primary/secondary reference standard including source and lot no. is required**.**
5.	**3.2.S.7**	According to the review literature of innovator brand storage condition of drug substance is 5°C±3°C with the retest period of 36months then justify the testing condition of given stability data of drug substance i.e. 30±2°C RH 65±5% & 40±2°C RH 75±5%.
6.	**3.2.P.2.2.1**	• Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80. • In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
7.	**3.2.P.5.2**	Clarification is required for not using reference standard/working standard for the preparation of standard solution as reflects from the given analytical procedures while performing the assay and dissolution of drug product.
8.	**3.2.P.5.3**	Justify for not performing the validation study on the same assay procedure which is given in section 3.2.P.5.2, specifically with reference to the preparation of both standard and sample preparation.Further , analytical method validation reports reflects that the assay procedure which has been validated is different from assay procedure given in section 3.2.P.5.2 and also not similar to the method specified in AMV protocol.
9.	**3.2.P.5.4**	Justify for not performing the content uniformity test while finished product analysis of drug product , since the test is included in the specification of finished drug product.
10.	**3.2.P.8**	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
11.	**2.3.R.1.1**	Justify for not adjusting the water content in the dispensing weight of API since the assay results are achieved on anhydrous as evident from the COA of API.

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

549.	Name, address of Applicant / Marketing Authorization Holder	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals Private Limited 31km Main 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. -6676 dated: 9th March 2023
	Details of fee submitted	PKR 30,000/-: dated 09/02/2023
	The proposed proprietary name / brand name	Ocalidon 10mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid…….10mg
	Pharmaceutical form of applied drug	Red colored, Round biconvex shaped, without any score, Film coated oral tablet
	Pharmacotherapeutic Group of (API)	Farnesoid X receptor agonists
	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	Ocaliva 10mg tablet by M/s Intercept Pharma Limited EMA Approved.
	For generic drugs (me-too status)	Abeticholic 10mg Tablet by M/s Dyson Research Laboratories Pvt. Ltd., Reg. No. 109522
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on dated 06-08-2019. Section approval letter issued on 05.11.2019
	Name and address of API manufacturer.	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu 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 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: (20171001, 20171101, 20171102)
	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 Ocaliva 10mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ocaliva 10mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) 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	Method validation studies have submitted including linearity,

	product	range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province China.		
API Lot No.	**20220802**		
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.	KA-22-001	KA-22-002	KA-22-003
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	28-10-2022	28-10-2022	28-10-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Gutain 30 mg and Gutain 60 mg capsule approved in 324 DRB Meeting
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. JS20191190 issued by Jiangsu Drug Administration valid till 29/11/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No. **K-1107632926281** dated 13/10/2022 is submitted wherein the permission to import different APIs including Obeticholic Acid for the purpose of test/analysis and stability studies is granted. • Invoice No. 22YX0049L dated 15/09/2022
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. S.4.1**	Justify for not including the test of parcticle size distribution, palladium test and solid state form test in the specification of drug substance by drug substance manufacturer, since these tests are included in the specification of drug substance of innovator product.
2.	**3.2.S.4.1-3.2.S.4.2**	• Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer 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". Since you have only submitted the specification and analytical procedure by drug substance manufacturer. • Submit detailed analytical procedure of drug substance by drug substance manufacturer, since the submitted procedure seems incomplete or only refer the general chapters of USP.
3.	**3.2.S.4.3**	• Justify for performing validation study of assay procedure which is different from the assay method by drug substance manufacturer given in section 3.2.S.4.2. • Further drug substance manufacturer used RID detector in the HPLC system for assay while the submitted chromatogram of validation studies reflect that the assay has performed by setting the wavelength of detector at 210nm, Justify for using the different detector from that specified by drug substance manufacturer.
4.	**3.2.S.5**	COA of primary/secondary reference standard including source and lot no. is required**.**
5.	**3.2.S.7**	According to the review literature of innovator brand storage condition of drug substance is 5°C±3°C with the retest period of 36months then justify the testing condition of given stability data of drug substance i.e. 30±2°C RH 65±5% & 40±2°C RH 75±5%.
6.	**3.2.P.2.2.1**	• Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80. • In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
7.	**3.2.P.5.2**	Clarification is required for not using reference standard/working standard for the preparation of standard solution as reflects from the given analytical procedures while performing the assay and dissolution of drug product.
8.	**3.2.P.5.3**	Justify for not performing the validation study on the same assay procedure which is given in section 3.2.P.5.2, specifically with reference to the preparation of both standard and sample preparation. Further , analytical method validation reports reflects that the assay procedure which has been validated is different from assay procedure given in section 3.2.P.5.2 and also not similar to the method specified in AMV protocol.
9.	**3.2.P.5.4**	Justify for not performing the content uniformity test while finished product analysis of drug product , since the test is included in the specification of finished drug product.
10.	**3.2.P.8**	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
11.	**2.3.R.1.1**	Justify for not adjusting the water content in the dispensing weight of API since the assay results are achieved on anhydrous as evident from the COA of API.

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

550.	Oral liquid syrup section (general) is approved vide letter No. F. 1-25/2008-Lic dated 17-09-2021.	
	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)
	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.706 : dated 09-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 67913763 dated 03-01-2023.
	The proposed proprietary name / brand name	SetBiz 5mg/5ml syrup.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cetirizine dihydrochloride 5mg (B.P Specifications)
	Pharmaceutical form of applied drug	Oral liquid.
	Pharmacotherapeutic Group of (API)	**R06AE07** Antihistamine
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	60ml,90ml,120ml,450ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA APPROVED
	For generic drugs (me-too status)	Citzin Syrup, NovaMed Pharmaceuticals, Reg. No. 063620.
	GMP status of the Finished product manufacturer	New license issued dated 14-09-2021 w.e.f. 13-09-2021.
	Name and address of API manufacturer.	Oral liquid syrup section (general) is approved vide letter No. F. 1-25/2008-Lic dated 17-09-2021.
	Module-II (Quality Overall Summary)	M/s Sreekara Organics India Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M), Sangareddy Dist-502325, Telangana, India.
	Module III (Drug Substance)	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.
	Stability studies	Official monograph of Cetirizine Hydrochloride is present in B.P. 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 substance

	Module-III (Drug Product):	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. Batches:(CZ/V/00411,CZ/V/00511& CZ/V/00611)
	Pharmaceutical equivalence and comparative dissolution profile	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.
	Analytical method validation/verification of product	Pharmaceutical Equivalence is established against the Citzin syrup manufactured by NovaMed pharmaceuticals Lahore by performing quality tests (Identification, filled volume, leakage teat, pH and Assay). Results of both the products are similar. CDP is not applicable.

STABILITY STUDY DATA

Manufacturer of API	M/s Sreekara Organics India Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M), Sangareddy Dist-502325, Telangana, India.		
API Lot No.	CTZ03521		
Description of Pack (Container closure system)	An amber glass bottle containing an-off white colored syrupy liquid with pleasant flavour, sealed with aluminum pp cap and packed in specific unitcarton.		
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-CS-001	RD-CS-001	RD-CS-001
Batch Size	500 bottles.	500 bottles.	500 bottles.
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	28-09-2022.	28-09-2022.	28-09-2022.
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 copy of approval of PolyBiz syrup in 322 minutes of meeting.
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:82408/TS/2022 issued by Drug Control Administration Government of Telangana issued on 15-03-2022and valid until 14-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted that the cetirizine dihydrochloride material of quantity 500g was obtained via loan from British Pharmaceuticals Lahore. Copy of documents already submitted in DRAP on dated 14-02-2023.

		• Copy of Form 3, 5 ,7 from & invoice (invoice# ZHI-CI/5465/0621) dated: 26-06-2021 cleared by DRAP Lahore office dated 12-07-2021 specifying import 100Kg Cetirizine 2HCl(Batch# CTZ03521)
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:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.S.7**	Justify for not including the test of pH determination and loss on drying test while performing the stability studies of drug substance.
2.	**3.2.P.1**	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
3.	**3.2.P.2.2.1**	Justify for performing the pharmaceutical equivalence against the comparator product instead of brand leader/ innovator / reference product.
4.	**3.2. P.4**	Submit the analysis report/COA of excipients propylene glycol and sorbitol, which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide No. F.6-30/2022-QA dated 21-10-2022.
5.	**3.2.P.5.2**	Justify for not adopting the assay procedure as recommended in BP monograph of Cetirizine Oral solution, since the conc of sample and standard solution specified in the assay method is different from the concentrations of solution mentioned in BP. Further the validation studies were also performed keeping the conc of sample and standard solution 0.1% while BP recommends 0.002% conc for both solutions in assay testing, then justify how the method comply BP specification.
6.	**3.2.P.8**	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Approval of API/ DML/ valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

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

551. Central Licensing Board in 278th meeting held on 10th &11th December,2020 has considered and approved additional section "Liquid Ampoule (SVP) General Section" of M/s Islam Pharmaceuticals, Sialkot.

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
	Dy. No. and date of submission	Dy. No. 22726 Dated: 11/08/2022
	Details of fee submitted	PKR 30,000/- Dated: 02/12/2021
	The proposed proprietary name / brand name	Diflo 75mg/3ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3ml ampoule contains: Diclofenac Sodium …….75mg
	Pharmaceutical form of applied drug	Clear and colorless solution filled in clear glass ampoules
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	3ml×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Econac Injection 75mg/3ml, MHRA Approved.
	For generic drugs (me-too status)	Voren injection 75mg/3ml by Asian Continental (Pvt.) Ltd. Reg. No. 007737
	GMP status of the Finished product manufacturer	New Section for liquid ampoule (SVP) General was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 18/12/2020
	Name and address of API manufacturer.	Shaanxi Xiyue Pharmaceutical Co., Ltd. Huashan town, huayin city, veinan city, shaanxi province 714200, 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)	Diclofenac sodium is as per USP 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 by HPLC (any individual impurity 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 06 months Batches:(1702201,1702202, 1702203)
	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 comparator product that is Voren injection 750mg/3ml injection by Asian Continental Pvt. Ltd. by performing quality

		tests (Appearance, Identification, Assay, pH and Volume Variation). All parameters results are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, Limit of Detection, Limit of Quantitation, Linearity, Range, Accuracy, Precision, Robustness.

STABILITY STUDY DATA

Manufacturer of API	Shaanxi Xiyue Pharmaceutical Co., Ltd. Huashan town, huayin city, veinan city, shaanxi province 714200, china.		
API Lot No.	2010205		
Description of Pack (Container closure system)	USP Type-I Clear Glass ampoules in PVC Tray, packed in unit carton (3ml×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: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21ARn048	21ARn049	21ARn050
Batch Size	2000 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	24-05-2021	24-05-2021	24-05-2021
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. (New Section)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SN20190340 issued by CFDA valid till 24/02/2024.
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 Diclofenac sodium for the purpose of test/analysis and stability studies is granted. • AirWay Bill No.607PVG91267326 Dated 22/12/2020
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:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.S.4.4**	Justify for not importing/using the sterile API for manufacturing of injection, since the results of sterility test and Bacterial Endotoxin test is not included in the COA of drug substance by both drug substance manufacturer and drug product manufacturer.

2.	**3.2.P.1**	• Clarify the role of benzyl alcohol in the applied formulation. • According to the literature of innovator brand the recommended quantity of Sodium metabisulphite is 2 mg per 3 ml and Benzyl alcohol is 120 mg per 3 ml, while the quantity of both excipients used in the applied formulation is different from the recommended quantity by the innovator, scientifically rationalize the quantity of both excipients used in the applied formulation.
3.	**3.2.P.2.2.1**	Justify for not performing the test of osmolality, particulate matter, sterility and Bacterial Endotoxin test while establishing the pharmaceutical equivalence against the reference product.
4.	**3.2.P.3.3**	Justify for preferring the aseptic filling procedure over terminal sterilization in the manufacturing procedure of drug product.
5.	**3.2.P.5.1**	• Submit reference of specification of pH test. • Justify for not including the test of osmolality in the finished product specification since it is the critical parameter in the injectable formulation.
6.	**3.2.P.8**	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Clarify the volume of glass ampoule use for primary packaging of drug product, since it is mentioned 1ml on stability data sheet while the applied formulation is of 3ml.
7.	**2.3.R.1.1**	Submit minimum handling capacity of the equipment used in the formulation of trail batches.

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

Agenda of Evaluator PEC-XX

Case No. 00 Registration applications of newly granted DML or New section (Human)

New License

M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat. The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has considered and approved the grant of Drug Manufacturing License to M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat by way of Formulation vide approval letter No. F. 1-8/2019-Lic dated 29th April, 2022 with following (03) sections:

S No.	Section
1	Tablet (General) section
2	Capsule (General) section
3	Cream/ointment (General) section

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, 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. 4379 dated 15/02/2023

	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Q-Pine 25mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)...25mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Psycholeptic, Diazepines, oxazepines, thiazepines and oxepines
	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)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 039621
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, 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, Solubility, 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, 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
	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: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
	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 have been established against the reference product that is **Seroquel tablet 25mg** Batch No 4983763 by ICI Pakistan Ltd, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product **Q-Pine**

		25mg tablet Batch No Q001. CDP has been performed against the same brand that **Seroquel tablet 25mg** in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and 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 accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA				
Manufacturer of API (pellets)	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India			
API Lot No.	LF-QUEF/112020/013			
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.	Q001	Q002	Q003	
Batch Size	1500 tablet	1500 tablet	1500 tablet	
Manufacturing Date	05-2022	05-2022	05-2022	
Date of Initiation	07-05-2022	09-05-2022	10-05-2022	
No. of Batches	03			

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Nil**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. G/25/2046 dated 16.05.2014 valid till 15.05.2019 issued by Food and Drug Administration ,Gujrat state, India .
3. I	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZHI-CI/5073/1220 dated 04-12-2020 for import of 55Kg of Quetiapine fumarate (Batch No LF-QUEF/112020/013) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020.
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	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC [XX]): **1.6.5** Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided **3.2.P.2.1.1** Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not provided. Since said ingredients are not found in innovator's formulation. **3.2.P.2** Parameters like Linearity and Range are not performed under product Analytical method verification study **3.2.P.2** Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study **3.2.P.8** Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
2.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, 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. 4378 dated 15/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Q-Pine 100mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)...100mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Psycholeptic, Diazepines, oxazepines, thiazepines and oxepines
	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)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 042222
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section

		Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, 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, Solubility, 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, 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
	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: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
	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 have been established against the reference product that is **Seroquel tablet 100mg** by ICI Pakistan Ltd, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product **Q-Pine 100mg tablet** CDP has been performed against the same brand that **Seroquel tablet 100mg** in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and 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 accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA	
Manufacturer of API (pellets)	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
API Lot No.	LF-QUEF/112020/013
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.	Q004	Q005	Q006
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	07-05-2022	09-05-2022	10-05-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Nil**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. G/25/2046 dated 16.05.2014 valid till 15.05.2019 issued by Food and Drug Administration ,Gujrat state, India .
3. I	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZHI-CI/5073/1220 dated 04-12-2020 for import of 55Kg of Quetiapine fumarate (Batch No LF-QUEF/112020/013) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Chromatograms for Batch No Q005 and Q006 were not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC [xx]):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.P.2.1.1 Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not Provided. Since said ingredient is not found in innovator's formulation.

3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study

3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study

3.2.P.2 Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided

3.2.P.8 Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.

3.2.P.8 Chromatograms for Batch No Q005 and Q006 to be submitted against each time point.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided

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

3.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.

	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, 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. 4617 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Q-Pine 200mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)...200mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Psycholeptic, Diazepines, oxazepines, thiazepines and oxepines
	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)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 053199
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, 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, Solubility, 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, 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
	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: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
	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 have been established against the reference product that is **Evokalm tablet 200mg** by M/s Pharmevo, Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product **Q-Pine 200mg tablet** CDP has been performed against the same brand that **Evokalm tablet 200mg** in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and 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 accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA

Manufacturer of API (pellets)	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India		
API Lot No.	LF-QUEF/112020/013		
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.	Q007	Q008	Q009
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	07-05-2022	09-05-2022	10-05-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Nil**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. G/25/2046 dated 16.05.2014 valid till 15.05.2019 issued by Food and Drug Administration ,Gujrat state, India .
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZHI-CI/5073/1220 dated 04-12-2020 for import of 55Kg of Quetiapine fumarate (Batch No LF-QUEF/112020/013) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020.

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

Remarks of Assessor (DD PEC [xx]):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.P.2.1.1 Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not Provided. Since said ingredients are not found in innovator's formulation.

3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study

3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study

3.2.P.2 Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided. Also justify selection of said brand instead of innovator.

3.2.P.8 Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided

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

4.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, 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. 4618 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Q-Pine 300mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)...300mg
	Pharmaceutical form of applied drug	Tablet

	Pharmacotherapeutic Group of (API)	Psycholeptic, Diazepines, oxazepines, thiazepines and oxepines
	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)	Rekyt Tablet by M/s High Q, Karachi Reg. No. 112752
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, 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, Solubility, 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, 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
	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: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
	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 have been established against the reference product that is **Evokalm tablet 300mg** by M/s Pharmevo, Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product **Q-Pine 300mg tablet** CDP has been performed against the same brand that **Evokalm tablet 300mg** in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and 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 accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA			
Manufacturer of API (pellets)	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India		
API Lot No.	LF-QUEF/112020/013		
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.	Q010	Q011	Q012
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	07-05-2022	09-05-2022	10-05-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Nil**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. G/25/2046 dated 16.05.2014 valid till 15.05.2019 issued by Food and Drug Administration ,Gujrat state, India .
3. I	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZHI-CI/5073/1220 dated 04-12-2020 for import of 55Kg of Quetiapine fumarate (Batch No LF-QUEF/112020/013) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	CoA Raw data sheet and Chromatograms for Batch No Q012 were not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC [xx]):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.P.2.1.1 Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not Provided. Since said ingredients are not found in innovator's formulation.

3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study

3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard,

placebo and blank) has not been provided under product Analytical method verification study **3.2.P.2** Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided. Moreover, registration status of Evokalm tablet 300mg to be provided. **3.2.P.8** Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it. **3.2.P.8** CoA Raw data sheet and Chromatograms for Batch No Q012 were not submitted against each time point. **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
5.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot#40, Street#S-6,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. 4615 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Deslor 5mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Desloratadine …….5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antihistamines
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarinex 5mg tablet by M/s Schering-Plough USFDA approved
	For generic drugs (me-too status)	Larinex 5mg Tablet by M/s Getz Pharma Pakistan, Reg. No. 039175
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API manufacturer.	M/s Smaart Pharmaceuticals Limited. B-22/23, MIDC, Ajanta Road, Jalgaon Maharashtra (India) - 425 003.
	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 Desloratadine is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubility, 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	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: (DH-1501, DH-1502, DH-1503)
	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 Clarinex 5mg tablet by M/s Schering-Plough Corporation (Batch No CL9562) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form, Disintegration time and microbial limit test). CDP has been performed against the same brand that is Clarinex 5mg tablet by M/s Schering-Plough Corporation 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 Smaart Pharmaceuticals Limited. B-22/23, MIDC, Ajanta Road, Jalgaon Maharashtra (India) - 425 003.		
API Lot No.	SMAART/DSL/2021/003		
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.	DS-01	DS-02	DS-03
Batch Size	2,000 tab	2,000 tab	2,000 tab

Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	10-05-2022	10-05-2022	10-05-2022
No. of Batches	03		

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted document (invoice No E-086/2020-2021) for import of 5Kg of Desloratadine (Batch No SMAART/DSL/2021/003) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 08-03-2021.
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)	Submitted

Remarks of Assessor (DD PEC[XX]):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Acceptance criteria/specifications for impurities (both single and total impurities) as mentioned in CoA from Drug Substance re different from those mentioned in USP. Justify it

3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study

3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study

3.2.P.2.1.1 Compatibility of the Drug Substance(s) with excipient (Magnesium stearate) is not Provided since said ingredient is not found in innovator's formulation.

3.2.P.8 Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 22-02-2021. Clarify it.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided.

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

6.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, 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. 4616 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Diflupine 150mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Fluconazole…….150mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use, triazole derivatives.
	Reference to Finished product specifications	BP
	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)	Diflucan 150mg Capsule By Pfizer Pakistan.
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Raj Pioneer Lab India, Pvt Ltd. 94-A,95-B & 96-A, Industrial area No. 01, A.B. Road Dewas, Madhya Pradesh, 455001,India.
	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, 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, 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
	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: RD/FCZ/001, RD/FCZ/002, RD/FCZ/003
	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 have been established against the reference product that is **Diflucan capsule 150mg (Batch No 1890017)** by M/s Pfizer Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product **Diflupine capsule (Batch No F001).** CDP has been performed against the same brand that **Diflucan capsule 150mg (Batch No 1890017)** in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and 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 accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA			
Manufacturer of API (pellets)	M/s Raj Pioneer Lab India, Pvt Ltd. 94-A,95-B & 96-A, Industrial area No. 01, A.B. Road Dewas, Madhya Pradesh, 455001,India.		
API Lot No.	FLC/FD/19/11/20-21		
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.	F001	F002	F003
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	05-06-2022	05-10-2022	05-11-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Nil**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
3. I	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted documents for import of 25Kg of Fluconazole (Batch No FLC/FD/19/11/20-21) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 22-02-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Provided

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

Remarks of Assessor (DD PEC [xx]):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study

3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study

3.2.P.8 Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 22-02-2021. Clarify it.

3.2.P.8 Analysis date mentioned for batches F002 and F003 at 0 month as 05/10/2022 (F002) and 05/11/2022 (F003) while date mentioned at 3rd month and 6th month as 08/08/2022 and 11/08/2022 respectively. Clarify it

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided.

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

7.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot#40, Street#S-6,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. 4614 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Moxopine 400mg tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin as HCl …….400mg
	Pharmaceutical form of applied drug	Light yellow color, oblong, biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Fluoroquinolone 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 400mg tablets by M/s Bayer Corporation, Approved in USFDA
	For generic drugs (me-too status)	Moxiget 400mg tablets by M/s Getz Pharma Pakistan, Reg. No. 047117

	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API manufacturer.	M/s Rini Life Sciences Pvt. Limited. RR Industrial Estate, Khasra No 115/2/3, Bhawrasla, Sanwer road, India.
	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, 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 Moxifloxacin HCl is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, 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	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: (MOX2000, MOX2001, MOX2002)
	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 Avelox 400mg tablets (Batch No AT9562) by M/s Bayer Corporation by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). against Test product i.e Moxopine tablet 400mg (Batch No MP-01) CDP has been performed against the same brand that is Avelox 400mg tablets (Batch No AT9562) by M/s Bayer Corporation 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, accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA	
Manufacturer of API	M/s Rini Life Sciences Pvt. Limited. RR Industrial Estate, Khasra No 115/2/3, Bhawrasla, Sanwer road, India.
API Lot No.	MH/002/09/2021
Description of Pack	Alu-Alu blister packed in unit carton

(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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MP-01	MP-02	MP-03
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	13-05-2022	13-05-2022	13-05-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Nil**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted documents for import of 50Kg of Moxifloxacin HCl (Batch No MH/002/09/2021) invoice no. GESAC2/3 dated 04.04.2022 wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned
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 provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC [xx]):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study

3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study.

3.2.P.2 Quantity of Lactose monohydrate used in innovator product as 68mg while firm used 87.8mg Lactose monohydrate in instant formulation. Justify it.

3.2.P.8 Documents for import of API (invoice no. GESAC2/3 dated 04.04.2022) was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, Clarify it. Moreover, approval from DRAP has not been provided.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided.

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

Agenda of Evaluator PEC-XXI

Agenda Item No. 01: Priority Applications of Human Drugs Locally Manufactured (New DML) applied on Form - 5F.

Case 01: M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura was granted License on 28-04-2022 with following sections: -

i. Tablet (General)
ii. Oral Dry Powder Suspension (General)
iii. Capsule (General)
iv. Sachet (General)

559.	Name, address of Applicant / Marketing Authorization Holder	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.
	Name, address of Manufacturing site.	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, 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. 5683 dated 28-02-2023
	Details of fee submitted	Slip No. 50746387584 PKR 30,000/- dated 02-02-2023
	The proposed proprietary name / brand name	D-Dex 30mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5% w/w Eq. to Dexlansoprazole ……30mg (Innovator's Specification)
	Pharmaceutical form of applied drug	White to greyish white colored dual delayed release pellets filled in hard gelatin capsule shell no.3 having light green color body and cap packed in Alu-Alu blister
	Pharmacotherapeutic Group of (API)	A02BC06, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1x10's, 2x7's, 3x10's, 10x10's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Dexilant 30 mg Capsules of M/s TAKEDA PHARMS USA (USFDA Approved).
	For generic drugs (me-too status)	Razodex 30mg Capsule (Reg. No. 086976) of M/s Getz Pharma.
	GMP status of the Finished product manufacturer	New DML granted dated 28-04-2022.
	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)	Official monograph of Dexlansoprazole is present In-house. 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 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 (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 Razodex 30mg 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 Razodex 30mg Capsule by Getz Pharma 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 been submitted including linearity, range, accuracy, precision, specificity and System Suitability.

STABILITY STUDY DATA				
Manufacturer of API		M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.		DLP881		
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: 06 months Accelerated: 06 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		CT007	CT008	CT009
Batch Size		1200 Capsules	1200 Capsules	1200 Capsules
Manufacturing Date		15-07-2022	15-07-2022	15-07-2022
Date of Initiation		22-07-2022	22-07-2022	22-07-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Nil		
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.3-26/2019-Addl.Dir. (QA&LT-I)-56 Dated 22-08-2022 is submitted.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 803107 Dated 29-06-2022 from M/s Vision Pharmaceuticals (local source) 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	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)	Submitted		

Remarks of Evaluator:

The following deficiencies / shortcomings have been communicated to the firm: -

i. The name of Firm as mentioned on enclosed DML is "M/s ICU Pharmaceuticals" whereas the Firm have mentioned the name as "M/s ICU Pharmaceuticals (SMC) (Pvt.) Ltd." throughout their application.

ii. 2.3.P.5.6 In Justification of Specifications, it has been mentioned that D-Dex 30mg Capsules are as per USP Specifications whereas in the rest of the application it has been mentioned as per In-house / Innovator's Specifications.

iii. 2.3 P.8.2 (a) In Stability Protocol for Commitment Batches, Testing Frequency has been mentioned as 0,3,6 Months only, the same shall be as per claimed Shelf Life of the Product.

iv. 3.2.P.2.2.1 In Tables given for Comparative Dissolution Profile Results, Buffer Stage pH 5.5 and pH 4.5 have been mentioned for same results in a table. Also Buffer Stage pH 7.0 and pH 6.8 have been mentioned for same results in a table.

v. 2.3.1 CTD Introduction has been mentioned of Moringa Pharma. Clarification is sought.

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

560.	Name, address of Applicant / Marketing Authorization Holder	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.
	Name, address of Manufacturing site.	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, 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. 5682 dated 28-02-2023
	Details of fee submitted	Slip No. 480770249565 PKR 30,000/- dated 02-02-2023
	The proposed proprietary name / brand name	D-Dex 60mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5% w/w Eq. to Dexlansoprazole ……60mg (Innovator's Specification)
	Pharmaceutical form of applied drug	White to greyish white colored dual delayed release pellets filled in hard gelatin capsule shell no.3 having light green color body and cap packed in Alu-Alu blister
	Pharmacotherapeutic Group of (API)	A02BC06, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1x10's, 2x7's, 3x10's, 10x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 60mg Capsules of M/s TAKEDA PHARMS USA (USFDA Approved).
	For generic drugs (me-too status)	Razodex 60mg Capsule (Reg. No. 086977) of M/s Getz Pharma.
	GMP status of the Finished product manufacturer	New DML granted dated 28-04-2022.

	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)	Official monograph of Dexlansoprazole is present In-house. 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 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 (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 Razodex 60mg 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 Razodex 60mg Capsule by Getz Pharma 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 been submitted including linearity, range, accuracy, precision, specificity and System Suitability.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad
API Lot No.	DLP881
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: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CT010	CT011	CT012
Batch Size	1200 Capsules	1200 Capsules	1200 Capsules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	26-07-2022	26-07-2022	26-07-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	Nil
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.3-26/2019-Addl.Dir. (QA&LT-I)-56 Dated 22-08-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 803107 Dated 29-06-2022 from M/s Vision Pharmaceuticals (local source) 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	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)	Submitted

Remarks of Evaluator:

The following deficiencies / shortcomings have been communicated to the firm: -

vi. The name of Firm as mentioned on enclosed DML is "M/s ICU Pharmaceuticals" whereas the Firm have mentioned the name as "M/s ICU Pharmaceuticals (SMC) (Pvt.) Ltd." throughout their application.

vii. 2.3.P.5.6 In Justification of Specifications, it has been mentioned that D-Dex 60mg Capsules are as per USP Specifications whereas in the rest of the application it has been mentioned as per In-house / Innovator's Specifications.

viii. 2.3 P.8.2 (a) In Stability Protocol for Commitment Batches, Testing Frequency has been mentioned as 0,3,6 Months only, the same shall be as per claimed Shelf Life of the Product.

ix. 3.2.P.2.2.1 In Tables given for Comparative Dissolution Profile Results, Buffer Stage pH 5.5 and pH 4.5 have been mentioned for same results in a table. Also Buffer Stage pH 7.0 and pH 6.8 have been mentioned for same results in a table.

x. 2.3.1 CTD Introduction has been mentioned of Moringa Pharma. Clarification is sought.

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

Case 02: M/s Himark Laboratories Private Limited Plot 37-A, Sundar Industrial Estate Lahore was granted New DML on 26-09-2019 with following sections: -

i. Tablet (General & General Antibiotics) Section.
ii. Capsule (General & General Antibiotics) Section.
iii. Dry Powder Suspension (General & General Antibiotics) Section.
iv. Sachet (General) Section.
v. Oral Liquid Syrup Section.
vi. Cream /Ointment (General) Section.

561.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited Lahore
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited Plot 37-A, 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. 4930 dated 21-02-2023
	Details of fee submitted	Slip No. 890870611016 PKR 20,000/- dated 31-01-2023 Slip No. 02554272360 PKR 10,000/- dated 04-11-2021
	The proposed proprietary name / brand name	Levomark 250 mg film coated tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet contains: Levofloxacin hemihydrate equivalent to Levofloxacin USP 250mg (USP Specifications)
	Pharmaceutical form of applied drug	Light yellow oblong film coated tablet
	Pharmacotherapeutic Group of (API)	J01MA12 Anti-infective for Systemic Use, Fluoroquinolones
	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	Levofloxacin 250 mg Film-coated Tablets by Accord Healthcare Limited UK (MHRA Approved).
	For generic drugs (me-too status)	Leflox 250mg Tablet (Reg. No. 026164) by Getz Pharma.
	GMP status of the Finished product manufacturer	New license granted on 26 – 09 – 2019.

	Name and address of API manufacturer.	Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd. 333 Jiangnan Road, hengdian, Dongyang, Zhejiang Province, 322118 PR 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 Levofloxacin hemihydrate 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 impurities and water content have been performed, 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:(LFA-V-20120801ES, LFA-V-20120802ES, LFA-V-20120803ES).
	Module-III (Drug Product):	The firm 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 Leflox 250mg Tablet by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Leflox 250mg Tablet by Getz Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) and 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 precision, accuracy and specificity.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd. 333 Jiangnan Road, hengdian, Dongyang, Zhejiang Province, 322118 PR China
API Lot No.	KY-LFA-M20190968E
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: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T-61	T-62	T-63
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	24-04-2020	24-04-2020	24-04-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	Nil
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190145 issued by China Food & Drugs Administration is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. 2020APE4256 dated 13 April 2020 is submitted. However approval from DRAP 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.	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:

The following deficiencies / shortcomings have been communicated to the firm: -

i. Latest GMP Inspection Report (not older than 03 years) is required.

ii. In Analytical Procedure for Levomark 250mg Film Coated Tablet (Document # SAP-106), under test for Dissolution, Medium has been mentioned as 0.1N HCl as well as 0.01N HCl. Clarification is required.

iii. In Stability Study Protocol for Levomark 250mg Film Coated Tablet (Document # SSP-024), the Objective has been stated as "to carry out stability of Levomark 250mg film coated Tablet (Loratadine)". Clarification is required.

iv. Evidence of approval from DRAP (concerned Assistant Director I&E) for procurement of Levofloxacin hemihydrate, API Lot No. KY-LFA-M20190968E is required.

v. Trial Batches were manufactured and placed on Stability in April 2020, however the application for Registration has been filed in February 2023 (with 06 Months Stability Data). Reason for delayed submission is sought.

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

Agenda of Evaluator PEC-XXII

Case no. 01: Registration applications of New DML (Veterinary)

a. New DML

I. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.

CLB in its 289th meeting held on 23-01-2023 has considered and approved the grant of DML by way of formulation with following sections.

1. **Oral Liquid (General) Veterinary**
2. **Oral Liquid (General Antibiotic) Veterinary**
3. **Oral Powder (General) Veterinary**
4. **Oral Powder (General Antibiotic) Veterinary**

Accordingly, firm has applied for following products for consideration by the Registration Board:

Section	No. of Products applied	No. of Molecules applied
Oral Liquid (General Antibiotic)	**23**	**10**

Oral Liquid (General Antibiotic)

562.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Feniczone-11 Oral Liquid
	Composition	Each 100ml contains: Florfenicol…11g Colistin Sulphate (BP)…50 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8107 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml : Decontrolled
	Me-too status	Flo Raft Oral Liquid of M/s Nawal Pharmaceuticals, Rawalpindi. (Reg. No. 078252)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
563.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Feniczone-12 Oral Liquid
	Composition	Each 100ml contains: Florfenicol…10g Colistin Sulphate (BP)…2.5g
	Diary No. Date of R& I & fee	Dy. No. 8106 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml : Decontrolled
	Me-too status	Co-Flor Liquid Mfg. by M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 078326)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	

564.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Feniczone-23 Oral Liquid
	Composition	Each 1000ml contains: Florfenicol…230g Colistin Sulphate (BP)…500 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8103 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml : Decontrolled
	Me-too status	SAFLOR-PLUS ORAL LIQUID Mfg. by M/s Sanna Laboratories, Faisalabad. (Reg. No. 088109)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
565.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Feniczone-25 Oral Liquid
	Composition	Each ml contains: Florfenicol…250mg Colistin Sulphate (BP)…0.5 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8104 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml : Decontrolled
	Me-too status	Poliflor Oral Liquid Mfg. by M/s Hawk Bio Pharma, Rawalpindi. (Reg. No. 078383)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
566.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Feniczone-10 Oral Liquid
	Composition	Each 100 ml contains: Florfenicol…10g Colistin Sulphate (BP)…50 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8105 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml : Decontrolled
	Me-too status	Florobex-C Oral Liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 078286)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	

567.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enc-Zone 10 Oral Liquid
	Composition	Each 100 ml contains: Enrofloxacin (BP Vet)…10g Colistin Sulphate (BP)…50 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8108 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Coliflox Solution Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 071082)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
568.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enc-Zone 200 Oral Liquid
	Composition	Each 1000 ml contains: Enrofloxacin (BP Vet)…200g Colistin Sulphate (BP)…500 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8109 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Floxatin 70 Oral Liquid Mfg. by M/s. elegance Pharmaceuticals, Rawalpindi. (Reg. No. 078282)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
569.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enc-Zone 48 Oral Liquid
	Composition	Each ml contains: Enrofloxacin (BP Vet)…100mg Colistin Sulphate (BP)…48 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8110 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Enromax Liquid Mfg. by M/s. Biogen Pharmaceuticals, Rawat. (Reg. No. 075618)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	

570.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enc-Zone 52 Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin (BP Vet)…10g Colistin Sulphate (BP)…52 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8111 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Bioenrocolis Liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 073916)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
571.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Cina-Zone 50 Oral Solution
	Composition	Each 1000ml contains: Enrofloxacin (BP Vet))…75g Sulphamethoxypyradazine (BP Vet)…50g Sulphamethazine (USP)…50g Trimethoprim (BP)…25g
	Diary No. Date of R& I & fee	Dy. No. 8113 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Sulphacina Oral solution Mfg. by M/s. Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074786)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Firm has applied a similar formulation with only difference being the strength of Sulphamethoxypyradazine as 75mg/ml but the claimed dosage form is Oral Suspension. Clarification required in this regard.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
572.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Cina-Zone 75 Oral Suspension
	Composition	Each ml contains: Enrofloxacin (BP Vet)…75mg Sulphamethoxypyradazine (BP Vet)…75mg Sulphamethazine (USP)…50mg Trimethoprim (BP)…25mg
	Diary No. Date of R& I & fee	Dy. No. 8112 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Cina T.S Oral Suspension Mfg. by M/s. Vety-Care Pharmaceuticals, Islamabad. (Reg. No. 031456)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Firm has already applied a similar formulation with only difference being the strength of Sulphamethoxypyradazine as 50mg/ml but the claimed dosage form is Oral Solution. Clarification required in this regard.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
573.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	T.S Zone 48 Oral Solution
	Composition	Each 100ml contains: Trimethoprim (BP)…8g Sulphadiazine (BP)…40g
	Diary No. Date of R& I & fee	Dy. No. 8114 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Fastrim-48 Liquid Mfg. by M/s. Mallard Pharmaceuticals, Multan. (Reg. No. 109803)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
574.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Toltrazone-5 Oral Solution
	Composition	Each 100ml contains: Toltrazuril…5g
	Diary No. Date of R& I & fee	Dy. No. 8115 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Coccidiostat/Antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Toltrasel Solution Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 071081)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
575.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Toltrazone-3 Oral Solution
	Composition	Each 1000ml contains: Toltrazuril…30g
	Diary No. Date of R& I & fee	Dy. No. 8116 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Coccidiostat/Antiprotozoal agent

	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Toltrasol 3% Liquid Mfg. by M/s. Intervac Pharma, Sheikhupura. (Reg. No. 069661)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
576.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Toltrazone-2.5 Oral Solution
	Composition	Each 1000ml contains: Toltrazuril…25g
	Diary No. Date of R& I & fee	Dy. No. 8117 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Coccidiostat/Antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Ultrazuriq Oral Solution Mfg. by M/s. Baariq Pharmaceuticals, Lahore. (Reg. No. 071093)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
577.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Colizone 48 Oral Solution
	Composition	Each 100ml contains: Colistin Sulphate (BP)…48 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8118 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Arkol Liquid Mfg. by M/s. Attabak Pharmaceuticals, Islamabad. (Reg. No. 028890)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
578.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Colizone 200 Oral Solution
	Composition	Each 1000ml contains: Colistin Sulphate (BP)…2,000,000,000 I.U
	Diary No. Date of R& I & fee	Dy. No. 8119 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications

	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Colibar Oral Solution Mfg. by M/s. Baariq Pharmaceuticals, Lahore. (Reg. No. 075784)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
579.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Tilmizone-25 Oral Solution
	Composition	Each ml contains: Tilmicosin Phosphate (USP)…250mg
	Diary No. Date of R& I & fee	Dy. No. 8120 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Tilcosin Oral Solution Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 035150)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
580.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enrozone-20 Oral Liquid
	Composition	Each ml contains: Enrofloxacin (BP Vet)…200mg
	Diary No. Date of R& I & fee	Dy. No. 8121 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Enroxsel 20 Oral Liquid Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 049364)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
581.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enrozone-10 Oral Liquid
	Composition	Each ml contains: Enrofloxacin (BP Vet)…100mg
	Diary No. Date of R& I & fee	Dy. No. 8122 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled

	Me-too status	Enrocin-10 20 Oral Solution Mfg. by M/s. Jfrin Pharmaceuticals, Karachi. (Reg. No. 043251)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
582.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enrozone-25 Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin (BP Vet)…25g
	Diary No. Date of R& I & fee	Dy. No. 8123 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Flunix Liquid Mfg. by M/s. Leads Pharma, Islamabad. (Reg. No. 043251)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
583.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Nora-Zone Oral Drench
	Composition	Each 100ml contains: Norfloxacin (BP)…20g Aminophylline (BP)…8g Guaifenesin (USP)…20g
	Diary No. Date of R& I & fee	Dy. No. 8124 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Nor Plus-20% Oral Liquid Mfg. by M/s. Bio Labs, Islamabad. (Reg. No. 033241)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
584.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Eca-Zone Oral Solution
	Composition	Each 1000ml contains: Enrofloxacin (BP Vet)…20g Colistin Sulphate (BP)…35g Amantadine (BP)…40g
	Diary No. Date of R& I & fee	Dy. No. 8125 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled

	Me-too status	Amantaflox-C Mfg. by M/s. Baariq Pharma, Lahore. (Reg. No. 073946)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	

Section	No. of Products applied	No. of Molecules applied
Oral Liquid (General)	**10**	**10**

Oral Liquid (General)

585.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Ati-Zone Oral Drench
	Composition	Each 100ml contains: Albendazole (BP)…10g Tricalbendazole (BP)…12g Ivermectin (USP)…0.2g
	Diary No. Date of R& I & fee	Dy. No. 8126 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Thunder Drench Mfg. by M/s. Star Laboratories, Lahore. (Reg. No. 058941)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of testing facility for the applied formulation.	
586.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Ati-Zone Oral Drench
	Composition	Each ml contains: Oxyclozanide (BP Vet)…62.5mg Oxyfendazole (BP Vet)…22.65mg Cobalt Sulphate…1.67mg Sodium Selenite (BP)…0.50mg
	Diary No. Date of R& I & fee	Dy. No. 8127 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Oxfendaox Plus Oral Drench Mfg. by M/s. Baariq Pharmaceuticals, Lahore. (Reg. No. 075786)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of testing facility for the applied formulation.	
587.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Oxazone Oral Drench
	Composition	Each ml contains: Oxyfendazole (BP Vet)…22.65mg
	Diary No. Date of R& I & fee	Dy. No. 8128 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Oxasel Drench Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 071084)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
588.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Levazone Oral Drench
	Composition	Each 100ml contains: Levamisole HCl (BP Vet)…1.5g Oxyclozanide (BP Vet)…3g
	Diary No. Date of R& I & fee	Dy. No. 8129 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Clozasol Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078328)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
589.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Levamizone Oral Drench
	Composition	Each ml contains: Levamisole HCl (BP Vet)…15mg
	Diary No. Date of R& I & fee	Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
590.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Scour-Zone Oral Solution
	Composition	Each ml contains: Sulphadiazine (BP)…33.500mg Neomycin Sulphate (BP)…1.800mg Pectin (USP)…7.100mg Vitamin B1 (BP)…0.150mg Sulphadimdine (BP Vet)…28.400mg

		Hyoscine Methyl Bromide (Ph. Eur)…0.040mg Kaolin (BP)…103.300mg Vitamin B2 (BP)…0.200mg
	Diary No. Date of R& I & fee	Dy. No. 8131 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antidiarrheal
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Scour-X Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 029661)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
591.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Sulpha-Zone Oral Solution
	Composition	Each 100ml contains: Sulphadimidine Sodium (BP)…33.3mg
	Diary No. Date of R& I & fee	Dy. No. 8132 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Sulphamic 33.33% Oral Liquid Mfg. by M/s. Intervac (Pvt.) Ltd., Sheikhupura. (Reg. No. 062197)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	
592.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Albendazole Oral Suspension
	Composition	Each 100ml contains: Albendazole (BP)…2.5g Cobalt Chloride (BP)…0.075g Sodium Selenite (BP)…0.035g
	Diary No. Date of R& I & fee	Dy. No. 8133 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Albenda Plus Suspension Mfg. by M/s. Farm Aid Group, Hattar. (Reg. No. 029670)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of testing facility for the applied formulation.	
593.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Febendazone Oral Liquid

	Composition	Each 100ml contains: Febendazole (USP)…12.5g Cobalt Sulphate…1.6g Zinc Carbonate…0.6g Sodium Selenite (USP)…3.0g
	Diary No. Date of R& I & fee	Dy. No. 8134 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Fenfas Liquid Mfg. by M/s. Intervac (Pvt.) Ltd., Sheikhupura. (Reg. No. 058753)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of testing facility for the applied formulation	
594.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Darvin Oral Solution
	Composition	Each 100ml contains: Sulphaquinoxaline (USP)…7.68g Diaverdine…1.92g
	Diary No. Date of R& I & fee	Dy. No. 8135 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Darvifas Oral Solution Mfg. by M/s. Intervac (Pvt.) Ltd., Sheikhupura. (Reg. No. 046610)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Ltr.	

Section	No. of Products applied	No. of Molecules applied
Oral Powder (General)	**12**	**09**

Oral Powder (General)

595.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Ectozone-96 Powder
	Composition	Each gram contains: Trichlorfon (USP)…960mg
	Diary No. Date of R& I & fee	Dy. No. 8091 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Ectofon Water Soluble Powder Mfg. by M/s. Prix Pharmaceuticals, Lahore. (Reg. No. 041295)

	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
596.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Ectozone-98 Powder
	Composition	Each gram contains: Trichlorfon (USP)…980mg
	Diary No. Date of R& I & fee	Dy. No. 8092 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Trifon Powder Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 071071)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
597.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Ectozone-100 Powder
	Composition	Each gram contains: Trichlorfon (USP)…1000mg
	Diary No. Date of R& I & fee	Dy. No. 8093 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	I-Trichlorophone Powder Mfg. by M/s. International Pharma Labs, Lahore. (Reg. No. 063617)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
598.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	ES-Zone 300 Oral Powder
	Composition	Each 100g contains: Sulphachloropyrazine Sodium as Sulphaclozine Sodium Monohydrate (USP)…30g
	Diary No. Date of R& I & fee	Dy. No. 8094 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Salcozine ST-30 Oral Powder Mfg. by M/s. Vetec Laboratories, Rawalpindi. (Reg. No. 097974)

	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
599.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Frusazone-4 Powder
	Composition	Each 1000g contains: Sodium Chloride (BP)…35g Magnesium Sulphate (BP)…35g Manganese Sulphate…1g Potassium Chloride…4g Furosemide (BP)…20g Calcium Carbonate (BP)…45g
	Diary No. Date of R& I & fee	Dy. No. 8095 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	F-Maars Powder Mfg. by M/s. D-Maarson Pharmaceuticals, Islamabad. (Reg. No. 078265)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of testing facility for the applied formulation.	
600.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	PCB-20 Oral Powder
	Composition	Each 100g contains: Paracetamol (BP)…20g Vitamin E (USP)…12.5g Vitamin C (BP)…5g Sodium Bicarbonate (BP)…12.5g Potassium Carbonate (BP)…12.5g
	Diary No. Date of R& I & fee	Dy. No. 8096 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anti-inflammatory, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Cemol Oral Powder Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 103909)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
601.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Parazone 6.7 Oral Powder
	Composition	Each 1000g contains: Acetylsalicylic Acid (BP)…67g Vitamin C (BP)…200g Sodium Citrate (BP)…7g

		Potassium Chloride (BP)…3g
	Diary No. Date of R& I & fee	Dy. No. 8097 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Analgesic/Vitamins
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Asperlyte-C Powder Mfg. by M/s. Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074789)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
602.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Amprozone-90 Water Soluble Powder
	Composition	Each 1000g contains: Amprolium HCl (USP)…900g
	Diary No. Date of R& I & fee	Dy. No. 8098 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Coccidiostat
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Amprobar Water Soluble Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore. (Reg. No. 073955)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
603.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Amprozone-50 Water Soluble Powder
	Composition	Each 100g contains: Amprolium HCl (USP)…50g
	Diary No. Date of R& I & fee	Dy. No. 8099 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Coccidiostat
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Amprocox-50 Water Soluble Powder Mfg. by M/s. Intervac (Pvt.) Ltd., Lahore. (Reg. No. 046601)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
604.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Cocozone Oral Powder

	Composition	Each 100g contains: Sulphaquinoxaline (USP)…16g Diaveridine…4g Vitamin A (BP)…0.40 MIU Vitamin K3 (USP)…1g
	Diary No. Date of R& I & fee	Dy. No. 8100 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Cocoplus Oral Powder Mfg. by M/s. Intervac Pharmaceuticals, Lahore. (Reg. No. 046604)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
605.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Saans Oral Powder
	Composition	Each 1000g contains: Bromhexine HCl (BP)…5000mg Prednisolone (BP)…200mg Guaifenesin (USP)…2600mg
	Diary No. Date of R& I & fee	Dy. No. 8101 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Mucolytic/corticosteroid/Expectorant
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Could not be confirmed in the applied combination.
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm could not be confirmed.
	Decision: Deferred for confirmation of me-too status.	
606.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Bromozone Water Soluble Powder
	Composition	Each 100g contains: Bromhexine HCl (BP)…5g
	Diary No. Date of R& I & fee	Dy. No. 8102 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Bromex Water Soluble Powder Mfg. by M/s. Attabak Pharmaceuticals, Islamabad (Reg. No. 058891)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022

	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	

Section	No. of Products applied	No. of Molecules applied
Oral Powder (Antibiotic)	**18**	**10**

Oral Powder (Antibiotic)

607.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	CNC-Zone Oral Powder
	Composition	Each 100g contains: Neomycin as Sulphate (BP)…7g Chlortetracyclin HCl (USP)…8g Colistin Sulphate (BP)…0.4g
	Diary No. Date of R& I & fee	Dy. No. 8073 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg : Decontrolled
	Me-too status	NCC Mix Mfg. by M/s. Prix Pharmaceuticals, Lahore (Reg. No. 069678
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
608.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Diarrozone Powder
	Composition	Each 12g contains: Neomycin sulphate (BP)…400mg Streptomycin sulphate (BP)…400mg Sulphaguanidine (BP)…4g Kaolin (BP)…4g Pectin (USP)…400mg Bismuth Subnitrate (USP)…2g Vitamin A Acetate (BP)…80000 IU
	Diary No. Date of R& I & fee	Dy. No. 8074 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Diarroban Oral Powder Mfg. by M/s. Star Labs, Lahore (Reg. No. 026438)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
609.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	LC-Zone Oral Powder

	Composition	Each gram contains: Lincomycin HCl (USP)…100mg Colistin sulphate (BP)…800000 IU
	Diary No. Date of R& I & fee	Dy. No. 8075 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Nobi-Lincol Oral Powder Mfg. by M/s. Noble Pharma, Mirpur AJK (Reg. No. 079116)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
610.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Linkzone-40 Powder
	Composition	Each gram contains: Lincomycin (as Lincomycin Hydrochloride) (USP) …400mg
	Diary No. Date of R& I & fee	Dy. No. 8076 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Lincosel 40 Powder Mfg. by M/s. Selmore Pharmaceuticals, Lahore (Reg. No. 089826)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
611.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Linkzone-1.1 Water Soluble Powder
	Composition	Each 1000g contains: Lincomycin HCl (USP)…11g
	Diary No. Date of R& I & fee	Dy. No. 8077 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Bio-Mycin Water soluble Powder Mfg. by M/s. Bio-Labs Pharmaceuticals, Islamabad (Reg. No. 082499)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

612.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Linkzone-1.1 Premix
	Composition	Each 1000g contains: Lincomycin HCl (USP)…110g
	Diary No. Date of R& I & fee	Dy. No. 8078 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Lincovet Premix Mfg. by M/s. Medi-vet, Lahore (Reg. No. 025397)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
613.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Linkzone-4.4 (Powder) Feed Premix
	Composition	Each 100g contains: Lincomycin HCl (USP)…4.4g
	Diary No. Date of R& I & fee	Dy. No. 8079 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Lincos-P Oral Powder Mfg. by M/s. A&K Pharmaceuticals, Faisalabad (Reg. No. 049667)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
614.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Linkozone-SS Oral Powder
	Composition	Each 100g contains: Lincomycin HCl (USP)…5g Spectinomycin (BP)…7.5g Spiramycinadipate (BP Vet)…2.5g Bromhexine HCl (BP)…0.5g
	Diary No. Date of R& I & fee	Dy. No. 8080 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications

	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Speclinx Oral Powder Mfg. by M/s. Vantage Pharmaceuticals, Faisalabad (Reg. No. 081714)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
615.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Spectin-100 Powder
	Composition	Each gram contains: Lincomycin HCl (USP)…33.3mg Spectinomycin Sulphate (BP)…66.7mg
	Diary No. Date of R& I & fee	Dy. No. 8081 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Specnolin Powder Mfg. by M/s. Mediexcel Pharmaceuticals, Faisalabad (Reg. No. 031401)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
616.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Spectin-1000 Powder
	Composition	Each gram contains: Lincomycin (as HCl) (USP)…335mg Spectinomycin (as Sulphate) (BP)…665mg
	Diary No. Date of R& I & fee	Dy. No. 8082 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	L-Spec Powder Mfg. by M/s. Mallard Pharmaceuticals, Multan (Reg. No. 046626)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
617.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Tylozone-C Oral Powder
	Composition	Each 1000g contains: Tylosin Tartarate (USP)…100g Doxycycline HCl (USP)…200g

		Colistin Sulphate (BP)…500 MIU Bromhexine HCl (BP)…5g
	Diary No. Date of R& I & fee	Dy. No. 8083 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Tycobar-D Oral Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 071099)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
618.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Tylozone 10 Oral Powder
	Composition	Each 1000g contains: Tylosin Tartarate (USP)…100g Doxycycline HCl (USP)…200g Colistin Sulphate (BP)…480 MIU Bromhexine HCl (BP)…5g
	Diary No. Date of R& I & fee	Dy. No. 8084 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Maxdox Water Soluble Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 087144)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
619.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Tylozone Oral Powder
	Composition	Each 1000g contains: Tylosin Tartarate (USP)…100g Doxycycline HCl (USP)…200g Colistin Sulphate (BP)…50g Bromhexine HCl (BP)…5g
	Diary No. Date of R& I & fee	Dy. No. 8085 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled

	Me-too status	CD Raas Oral Powder Mfg. by M/s. Zakfas Pharmaceuticals, Multan (Reg. No. 057072)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
620.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Tylozone-40 Oral Powder
	Composition	Each 100g contains: Tylosin Tartarate (USP)…20g Doxycycline HCl (USP)…40g Colistin Sulphate (BP)…10g Bromhexine HCl (BP)…2g
	Diary No. Date of R& I & fee	Dy. No. 8086 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	MultiDox Oral Powder Mfg. by M/s. Hawk Bio Pharmaceuticals, Islamabad (Reg. No. 078395)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg. **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
621.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Tiazone-10 Oral Soluble Powder
	Composition	Each 100g contains: Tiamulin Hydrogen Fumarate (USP)…10g Chlortetracycline Hydrochloride (USP)…30g
	Diary No. Date of R& I & fee	Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack size of upto 1Kg.	
622.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Fosfozone Dry Powder
	Composition	Each gram contains: Fosfomycin (Calcium salt) (BP)…250mg
	Diary No. Date of R& I & fee	Dy. No. 8088 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Cannot be confirmed.
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Me-too status required for applied formulation.
	Decision: Deferred for confirmation of me-too status.	
623.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Amazone-10 Oral Powder
	Composition	Each 1000g contains: Amantadine HCl (BP)…100g
	Diary No. Date of R& I & fee	Dy. No. 8089 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Rescue-100 Oral Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 079812)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
624.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Amazone-98 Oral Powder
	Composition	Each 100g contains: Amantadine HCl (BP)…98g
	Diary No. Date of R& I & fee	Dy. No. 8090 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Amadine-98 Oral Powder Mfg. by M/s. Aptly Pharmaceuticals, Faisalabad (Reg. No. 093841)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	

Case No. 02 – Routine registration application of Veterinary Drugs on Form-5 (Local).

625.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Kryptin Oral Liquid

	Composition	Each ml contains: Enrofloxacin (EP)….75mg Sulphamethoxypyrizadine (EP)…75mg Sulphamethazine (USP)…50mg Trimethoprim (EP)…25mg
	Diary No. Date of R& I & fee	Dy. No. 1192 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	Me-too status	Cina TS Oral Suspension Mfg. by M/s. Vety care Pharmaceuticals, Islamabad (Reg. No. 031456)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
626.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Age-Kryp Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin (EP)….10mg Aminophylline (BP)…4g Guaifenesin (USP)…10g
	Diary No. Date of R& I & fee	Dy. No. 1196 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic/Expectorant/Bronchodilator
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	Me-too status	EG Enro plus liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 074099)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
627.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP-Dotylo C Oral Powder
	Composition	Each 1000g contains: Tylosin Tartarate (EP)….100g Doxycyline (BP)…200g Colistin Sulphate (BP)…30g
	Diary No. Date of R& I & fee	Dy. No. 1168 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50g, 100g, 250g, 500g, 450g, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg : Decontrolled
	Me-too status	Doxi-Tol Powder Mfg. by M/s. Leads Pharma, Islamabad (Reg. No. 057053)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.

	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Approved. Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
628.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP-Bromo Oral Liquid
	Composition	Each 100ml contains: Bromhexine HCl (BP)…5g
	Diary No. Date of R& I & fee	Dy. No. 1220 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	Me-too status	Bromo Shell Liquid Mfg. by M/s. Inshal Pharmaceuticals, Islamabad (Reg. No. 075762)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Approved with innovator's specifications and pack size of upto 1L. 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 07-05-2021, before issuance of registration letter..	
629.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP-Colineocin Oral Powder
	Composition	Each 1000g contains: Chlortetracycline (BP)…80g Neomycin Sulphate (BP)…70g Colistin Sulphate (BP)…4g Bromhexine HCl (BP)…5g
	Diary No. Date of R& I & fee	Dy. No. 1196 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50g, 100g, 200g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25K : Decontrolled
	Me-too status	Q.NCC 200 Powder Mfg. by M/s. Mallard Pharmaceuticals, Multan (Reg. No. 079222)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Approved with innovator's specifications and pack size of upto 1Kg. Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
630.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP-Resto D Oral Powder

	Composition	Each 1000g contains: Tylosin Tartarate (EP)…100g Doxycycline HCl (BP)…200g Colistin Sulphate (BP)… 500 MIU Bromhexine (EP)…5g Phenylbutazone (USP)…12g
	Diary No. Date of R& I & fee	Dy. No. 1181 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50g, 100g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg : Decontrolled
	Me-too status	Resco Powder Mfg. by M/s. Leads Pharmaceuticals, Islamabad (Reg. No. 044965)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product. ii. Firm has not provided the conversion of Colistin Suphate from MIU to grams.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
631.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP-Fosco Oral Powder
	Composition	Each 100g contains: Fosfomycin Calcium (EP)…20g Fructose (EP)…18g Tylosin Tartarate (EP)…10g Sodium Phosphate (BP)…15g Magnesium Sulphate (USP)…10g
	Diary No. Date of R& I & fee	Dy. No. 1179 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50g, 100g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg : Decontrolled
	Me-too status	Fosfotyl Powder Mfg. by M/s. Leads Pharmaceuticals, Islamabad (Reg. No. 078240)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Deferred for submission of drug product analytical procedure along with evidence of requisite testing facility, for the applied formulation.	
632.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	T Fluton D Oral Powder
	Composition	Each Kg contains: Tylosin Tartarate (EP)…10% Doxycycline (BP)…20%
	Diary No. Date of R& I & fee	Dy. No. 1215 dated 08-01-2021, Rs. 20,000/- Dated 07-01- 2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications

	Pack size & Demanded Price	50g, 100g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg : Decontrolled
	Me-too status	Biodox-T Powder Mfg. by M/s. Bio Labs, Islamabad (Reg. No. 028541)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Approved **Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
633.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Strepto-Kyp Oral Powder
	Composition	Each 1000g contains: Tylosin Tartarate (EP)…10% Doxycycline Hyclate (BP)…20% Colistin Sulphate (BP)…450 MIU Bromhexine HCl (EP)…0.5% Streptomycin Sulphate (EP)…3.6%
	Diary No. Date of R& I & fee	Dy. No. 1203- dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50g, 100g, 200g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg : Decontrolled
	Me-too status	Biodox-T Powder Mfg. by M/s. Nobel Pharma Mirpur, AJ&K (Reg. No. 075609)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product. ii. Firm has not provided the conversion of Colistin Suphate from MIU to grams or %.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
634.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP T.S Oral (Antibiotic Oral Liquid)
	Composition	Each 1000ml contains: Tylosin Tartarate (EP)…50g Sulphamethoxypyridazine (EP)…50g Trimethoprim (EP)…10g Bromhexine HCl (EP)…5g
	Diary No. Date of R& I & fee	Dy. No. 1182 - dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	Me-too status	Compli Plus Liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 073998)
	GMP status	Inspection for issuance of DML conducted on 12-10-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.

	Decision: Approved with innovator's specifications and pack size of upto 1L. Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
635.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Bromocol-E Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin as HCl…10g Colistin Sulphate…5 MIU Bromhexine…0.50%
	Diary No. Date of R& I & fee	Dy. No. 1792 - dated 13-01-2021, Rs. 20,000/- Dated 23-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 1000ml : Decontrolled
	Me-too status	Compli Plus Liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 073998)
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Valid Form-5 with signature of authorised person/applicant is required. ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. v. Firm has claimed Manufacturers specifications for finished product. vi. Firm has not provided the conversion of Colistin Suphate from MIU to grams.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
636.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Oxyfloro-N Oral Powder
	Composition	Each Kg contains: Neomycin Sulphate (BP)…150g Florfenicol…100g Oxytertacyclin HCl (BP)…300
	Diary No. Date of R& I & fee	Dy. No. 1788 - dated 13-01-2021, Rs. 20,000/- Dated 06-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100g, 200g, 250g, 500g, 1000g : Decontrolled
	Me-too status	Neoxflor Oral Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 088638)
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Valid Form-5 with signature of authorised person/applicant is required.

		ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. v. Firm has claimed Manufacturers specifications for finished product.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
637.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Cocxifas Super Powder
	Composition	Each gram contains: Amprolium HCl…166mg Sulphaquinoxaline…166mg Colistin Sulphate…50000 IU Vitamin A…50000 IU Vitamin K…5mg
	Diary No. Date of R& I & fee	Dy. No. 1785 - dated 13-01-2021, Rs. 20,000/- Dated 29-12-2020
	Pharmacological Group	Antibiotic & Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100g, 200g, 250g, 500g, 1000g : Decontrolled
	Me-too status	Me-too status cannot be confirmed.
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Me-too status cannot be confirmed. ii. Valid Form-5 with signature of authorised person/applicant is required. iii. Valid copy of DML is required iv. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. v. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. vi. Firm has claimed Manufacturers specifications for finished product. vii. Firm has not provided the conversion of Colistin Suphate from MIU to grams.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
638.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Amidiofas Plus Powder
	Composition	Each Kg contains: Amprolium…200mg Furaltadone…200mg Vitamin A…4000000 IU Vitamin D3…2000000 IU Vitamin K3…10g
	Diary No. Date of R& I & fee	Dy. No. 1790 - dated 14-01-2021, Rs. 20,000/- Dated 06-01-2021

	Pharmacological Group	Antibiotic, Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100g, 200g, 250g, 500g, 1000g : Decontrolled
	Me-too status	Me-too status cannot be confirmed.)
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Me-too status cannot be confirmed. ii. Valid Form-5 with signature of authorised person/applicant is required. iii. Valid copy of DML is required iv. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. v. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. vi. Firm has claimed Manufacturers specifications for finished product.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
639.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Bensel Injection
	Composition	Each ml contains: Lincomycin (as HCl)…40mg Spectnomycin (as HCl)…80mg Benzyl Alcohol…9mg
	Diary No. Date of R& I & fee	Dy. No. 1789 - dated 14-01-2021, Rs. 20,000/- Dated 29-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml : Decontrolled
	Me-too status	LSA Injection Mfg. by M/s. Leads Pharma, Islamabad (Reg. No. 063724)
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Valid Form-5 with signature of authorised person/applicant is required. ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. v. Firm has claimed Manufacturers specifications for finished product.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
640.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.

	Brand Name +Dosage Form + Strength	Intermox-G Injection
	Composition	Each ml contains: Amoxicillin Trihydrate eq. to Amoxicillin (BP)…150mg Gentamycin Sulphate eq to Gentamycin (BP)…40mg
	Diary No. Date of R& I & fee	Dy. No. 1791 - dated 14-01-2021, Rs. 20,000/- Dated 23-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml : Decontrolled
	Me-too status	Me-too status cannot be confirmed.
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Me-too status cannot be confirmed. ii. Valid Form-5 with signature of authorised person/applicant is required. iii. Valid copy of DML is required iv. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. v. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. vi. Firm has claimed Manufacturers specifications for finished product.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
641.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Multimax Injection
	Composition	Each 100ml contains: L-CaR&Itne (USP)…500mg Pyridoxine Hydrochloride (BP)…15mg Cyanocobalamin (BP)…3mg DL-Acetyl methionine (MS)…2000mg L-Arginine (BP)…240mg L-Citruline (MS)…120mg Glycine (BP)…150mg Aspartic Acid (BP)…150mg Fructose (BP)…5000mg Thioctic Acid (BP)…20mg L-OR&Ithine (MS)…120mg L-Lysine (USP)…50mg Taurine (USP)…150mg Glutamic Acid (BP)…150mg Sorbitol (BP) 8000mg
	Diary No. Date of R& I & fee	Dy. No. 1786 - dated 14-01-2021, Rs. 20,000/- Dated 29-12-2020
	Pharmacological Group	Amino Acids and Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	250ml : Decontrolled
	Me-too status	Multimino-V Injection Mfg. by M/s. Selmore Pharmaceuticals, Lahore (Reg. No. 058712)

	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Valid Form-5 with signature of authorised person/applicant is required. ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. v. Firm has claimed Manufacturers specifications finished product.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
642.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Gentafas 15% Injection
	Composition	Each ml contains: Gentamycin Sulphate…150mg
	Diary No. Date of R& I & fee	Dy. No. 1784 - dated 14-01-2021, Rs. 20,000/- Dated 08-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml : Decontrolled
	Me-too status	Me-too status cannot be confirmed.
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Me-too status cannot be confirmed. ii. Valid Form-5 with signature of authorised person/applicant is required. iii. Valid copy of DML is required iv. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. v. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. vi. Firm has claimed Manufacturers specifications for finished product.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
643.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Gentafas 20% Injection
	Composition	Each ml contains: Gentamycin as Sulphate (BP)…200mg
	Diary No. Date of R& I & fee	Dy. No. 1787 - dated 14-01-2021, Rs. 20,000/- Dated 08-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml : Decontrolled

	Me-too status	Gentabar-20 Injection Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 087121)
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Valid Form-5 with signature of authorised person/applicant is required. ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. v. Firm has claimed Manufacturers specifications for finished product.
	Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

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

a. New cases

644.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	OLAM tablet 20/5mg
	Composition	Each film coated tablet contains: Amlodipine…….20mg Olmesartan Medoxomil ……5mg
	Diary No. Date of R& I & fee	Dy No. 14588 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789191 dated 07-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code C09DB02
	Type of Form	Form 5
	Finished Product Specification	Not mentioned by applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Finished product specifications are required. • Evidence of approval of applied product in reference regulatory authority is required. • 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.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or change in formulation as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.** • **Submission of finished product specifications.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
645.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	CARDIMAX 35mg tablet
	Composition	Each film coated modified release tablet contains: Trimetazine dihydrochloride…… 35mg
	Diary No. Date of R& I & fee	Dy No. 16728 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792370 dated 06-03-2019.
	Pharmacological Group	Other cardiac preparations ATC Code C01EB15 (Trimetazidine)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Innovator's Specifications; Trimetazidine hydrochloride tablets monograph is available in JP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Trimetazidine biogaran 35 mg, film-coated tablet with modified release ANSM approved
	Me-too status	Ofimta MR tablet 35mg High-Q Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Change of name from Trimetazine to Trimetazidine is required on cover letter and other points in Form 5 along with requisite fee. • Change in specifications from innovator's specifications to JP is required along with requisite fee.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years.** • **Change of name from Trimetazine to Trimetazidine on cover letter and other points in Form 5 along with along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Change in specifications from innovator's specifications to JP along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**	
646.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	BISOCAR tablet 5mg
	Composition	Each film coated tablet contains: Bisoprolol fumarate…... 5mg
	Diary No. Date of R& I & fee	Dy No. 14594 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792384 dated 06-03-2019.
	Pharmacological Group	Beta blocking agents, selective ATC Code C07AB07
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bisoprolol fumarate 5 mg film-coated tablets Marketing Authorization Holder: Generics [UK] Limited t/a Mylan, UK. MHRA Approved
	Me-too status	Saibiso Tablet by Saibins Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
647.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	OFLO tablet 200mg
	Composition	Each film coated tablet contains: Ofloxacin……....200mg
	Diary No. Date of R& I & fee	Dy No. 14575 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789178 dated 07-03-2019.
	Pharmacological Group	Fluoroquinolones ATC Code J01MA01
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ofloxacin 200mg film coated tablets Company: Teva UK Ltd MHRA Approved
	Me-too status	Ofloper 200mg Tablet Quaper Pvt Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
648.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Capsule section (General)
	Brand Name +Dosage Form + Strength	VENFAX- SR Capsules 75mg
	Composition	Each extended release capsule contains: Extended release pellets of Venlafaxine Hydrochloride equivalent to Venlafaxine……75mg
	Diary No. Date of R& I & fee	Dy No. 14598 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792388 dated 06-03-2019.
	Pharmacological Group	Other antidepressants ATC Code N06AX16
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alventa XL 75 mg prolonged-release capsules, hard MHRA Approved
	Me-too status	Venwell XR 75mg Capsule FYNK Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Source of pellets is not provided; source of pellets along with GMP certificate of that source, stability study of three batches of pellets and certificate of analysis of pellets are required. In case of imported pellets, requisite fee is also required.
	Decision: Deferred for following: • **Source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.** • **Latest GMP inspection report conducted within last three years.**	
649.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	VENFAX- SR Capsules 37.5mg
	Composition	Each extended release capsule contains: Extended release pellets of Venlafaxine Hydrochloride equivalent to Venlafaxine……37.5mg
	Diary No. Date of R& I & fee	Dy No. 14597 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792387 dated 06-03-2019.
	Pharmacological Group	Other antidepressants ATC Code N06AX16
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alventa XL 37.5 mg prolonged-release capsules, hard MHRA Approved
	Me-too status	Fix-Zar 37.5mg XR Capsule Invictus Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Source of pellets is not provided; source of pellets along with GMP certificate of that source, stability study of three batches of pellets and certificate of analysis of pellets are required. In case of imported pellets, requisite fee is also required.
	Decision: Deferred for following: • **Source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.** • **Latest GMP inspection report conducted within last three years.**	
650.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	BISOCAR tablet 2.5mg
	Composition	Each film coated tablet contains: Bisoprolol fumarate…….....2.5mg
	Diary No. Date of R& I & fee	Dy No. 16726 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792366 dated 06-03-2019.
	Pharmacological Group	Beta blocking agents, selective ATC Code C07AB07
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bisoprolol fumarate 2.5 mg film-coated tablets PL 04569/1255 Marketing Authorization Holder: Generics [UK] Limited t/a Mylan, UK. MHRA Approved
	Me-too status	Saibiso Tablet by Saibins Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
651.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	AVENT 16mg tablet
	Composition	Each film coated tablet contains: Candesartan Cilexetil……. 16mg
	Diary No. Date of R& I & fee	Dy No. 14605 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792395 dated 06-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain ATC Code C09CA06
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan Cilexetil 16 mg Tablets - PL 35084/0002-9; MHRA Approved (for uncoated tablet).
	Me-too status	Cansaar 8mg Tablet (uncoated) M/s Pharmatec Pakistan Karachi
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Applied product is film coated tablet. Evidence of product approved in reference regulatory authority is of uncoated tablets. Approval of film coated tablet in reference regulatory authority or change of formulation from film coated to uncoated tablet along with requisite fee is required.
	Decision: Deferred for following: • **Change in formulation from film coated to uncoated tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
652.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	DESVEN tablet 50mg
	Composition	Each film coated tablet contains: Desvenlafaxine…….....50mg
	Diary No. Date of R& I & fee	Dy No. 14608 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792399 dated 06-03-2019.
	Pharmacological Group	Other antidepressants ATC Code N06AX23
	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.	Extended release tablet (DIN 02535106) is Health Canada approved.
	Me-too status	Desven XR 50mg Tablet (For extended release tablet) Pharmevo (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Finished product specifications are not provided. • Applied product is film coated tablet. Formulation approved in reference regulatory authority (Health Canada) and in Pakistan is extended release tablet. Change in formulation from film coated to extended release tablet along with relevant fee is required.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years.** • **Provision of finished product specifications.** • **Change in formulation from film coated to extended release tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**	
653.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)

	Brand Name +Dosage Form + Strength	ZYTRIN 2mg tablet
	Composition	Each tablet contains: Terazosin (as Hydrochloride.$2H_20$)…… 2mg
	Diary No. Date of R& I & fee	Dy No. 14582 dated 07-03-2019 Fee paid PKR 20,000 vide Deposit Slip No. 0789185 dated 07-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code G04CA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Terazosin 2 mg Tablets MHRA Approved PL 43870/0001
	Me-too status	Euzet 2mg Tablet Trigon Pharmaceuticals (Private) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
654.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	ZYTRIN 5mg tablet
	Composition	Each tablet contains: Terazosin (as Hydrochloride.$2H_20$)…… 5mg
	Diary No. Date of R& I & fee	Dy No. 14583 dated 07-03-2019 Fee paid PKR 20,000 vide Deposit Slip No. 0789186 dated 07-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code G04CA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Terazosin 5 mg Tablets MHRA Approved PL 43870/0002
	Me-too status	Euzet 5mg Tablet Trigon Pharmaceuticals (Private) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
655.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	MEF tablets 500mg
	Composition	Each film coated tablet contains: Mefenamic acid…….500mg
	Diary No. Date of R& I & fee	Dy No. 14574 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789177 dated 07-03-2019.
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, non-steroids ATC Code M01AG01
	Type of Form	Form 5

	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mefenamic acid 500 mg film-coated tablets MHRA Approved PL 13606/0258
	Me-too status	Megamef 500mg Tablet Mega Pharmaceuticals Limited
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
656.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	RIFAREX tablet 550mg
	Composition	Each film tablet contains: Rifaxamin…….…….550mg
	Diary No. Date of R& I & fee	Dy No. 14579 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789182 dated 07-03-2019.
	Pharmacological Group	Antibiotics ATC Code A07AA11
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xifaxan 550 mg film coated tablets USFDA Approved
	Me-too status	Nyxia 550mg film coated tablet Pharmedic Laboratories (Pvt.) Ltd Lahore
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
657.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	D-FEN SR tablet 100mg
	Composition	Each delayed release tablet contains: Diclofenac Sodium ……100mg
	Diary No. Date of R& I & fee	Dy No. 14568 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789171 dated 07-03-2019.
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, non-steroids ATC Code M01AB05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available as 100mg delayed release oral tablet
	Me-too status	Not available as 100mg delayed release oral tablet
	GMP status	Last GMP inspection conducted on 10-07-2019

	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. • 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.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or change in formulation as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
658.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Capsule section (General)
	Brand Name +Dosage Form + Strength	OSPRA-PLUS Capsules 20/1100mg
	Composition	Each capsule contains: Omeprazole……..20mg Sodium bicarbonate …….1100mg
	Diary No. Date of R& I & fee	Dy No. 14576 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789179 dated 07-03-2019.
	Pharmacological Group	Proton pump inhibitors ATC Code A02BC01
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zegerid capsule USFDA Approved
	Me-too status	Outset Capsules GT Pharma (Pvt) Ltd., Lahore Reg. No. 86378
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
659.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	LEFNO tablet 20mg
	Composition	Each film coated tablet contains: Lefnu……...20mg
	Diary No. Date of R& I & fee	Dy No. 14609 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792400 dated 06-03-2019.
	Pharmacological Group	Selective immunosuppressants ATC Code L04AA13
	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.	Arava 20mg USFDA Approved
	Me-too status	Leforex 20mg tablet DeMont Research Laboratories (Pvt) Ltd., Sheikhupura
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Product is available in BP. Finished product specifications are required. • Change in label claim to read: "Each film coated tablet contains: Leflunomide……...20mg", along with requisite fee.
	Decision: Deferred for following: • **Change in label claim to read** **"Each film coated tablet contains:** • **Leflunomide……...20mg", along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Change in product specifications to BP Specifications.** • **Latest GMP inspection report conducted within last three years.**	
660.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	LAXMAC tablet 60mg
	Composition	Each film coated tablet contains: Loxoprefen Sodium as Hydrate…….60mg
	Diary No. Date of R& I & fee	Dy No. 14571 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789174 dated 07-03-2019.
	Pharmacological Group	Analgesic, anti-inflammatory, anti-pyretic
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available for film coated tablet and applied composition
	Me-too status	Loxonin 60mg film coated tablet Evolution Pharmaceuticals (Pvt.) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Composition approved in PMDA Japan is Loxoprofen sodium hydrate (JP) 68.1mg (Brand name Kunihiro) whereas applied composition is Loxoprefen Sodium as Hydrate 60mg. Change in composition according to RRA is required along with relevant fee. • Applied product is film coated tablet. Evidence of product approved in PMDA, Japan is of uncoated tablets. Approval of film coated tablet in reference regulatory authority or change of formulation from film coated to uncoated tablet along with prescribed fee is required.
	Decision: Deferred for following: • **Change in formulation from film coated to uncoated tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

	• **Change in composition from Loxoprefen Sodium as Hydrate 60mg to Loxoprofen sodium hydrate (JP) 68.1mg as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021 (full fee of registration).** • **Latest GMP inspection report conducted within last three years.**	
661.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	Dexamax Cream 5%w/w
	Composition	Each gram cream contains: Dexamethasone Sodium Phosphate……. 5% w/w
	Diary No. Date of R& I & fee	Dy No. 16727 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 072369 dated 07-03-2019
	Pharmacological Group	Corticosteroids, moderately potent (group II) ATC Code D07AB19
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of separate dispensing facility for dispensing of steroidal materials 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 is required. • 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.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years clearly mentioning availability of separate dispensing facility or otherwise, for dispensing of steroidal raw materials.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or change in formulation as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
662.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	Skinton 20% Cream
	Composition	Each gram of cream contains: Azelaic acid..……0.2gm/gm
	Diary No. Date of R& I & fee	Dy No. 16724 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0804196 dated 07-03-2019
	Pharmacological Group	Other anti-acne preparations for topical use ATC Code D10AX03

	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azelex 20% topical cream USFDA Approved
	Me-too status	Ezalic 20% cream Evolution Pharmaceuticals (Pvt.) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Change of label claim according to composition given in USFDA, as follows: "Each gram of cream contains Azelaic acid.....0.2 gm (20% w/w)" along with requisite fee.
	Decision: Deferred for following: • **Change of label claim according to composition given in USFDA, as follows:** • **"Each gram of cream contains Azelaic acid.....0.2 gm (20% w/w)" along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
663.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	PERLIC 1% cream
	Composition	Each gram of cream contains: Lindane…..…....0.01gm/gm
	Diary No. Date of R& I & fee	Dy No. 14591 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789195 dated 07-03-2019
	Pharmacological Group	Ectoparasiticides, including Scabicides ATC Code P03AB02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Line Cream Shaigan Pharmaceuticals (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. • Change of label claim according to label claim of me-too product, as follows: "Each gram of cream contains Lindane.....10mg" along with requisite fee.
	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,** • **Latest GMP inspection report conducted within last three years.** • **Change of label claim according to label claim of me-too product, as follows:** **"Each gram of cream contains Lindane.....10mg" along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**	

664.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	NCIN Ointment 5%w/w
	Composition	Each gram contains: Neomycin sulphate…….5% w/w
	Diary No. Date of R& I & fee	Dy No. 14601 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792391 dated 06-03-2019
	Pharmacological Group	Other antibiotics for topical use ATC Code D06AX04
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Not found in applied strength
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. • 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.
	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 applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Latest GMP inspection report conducted within last three years.**	
665.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	LURBI GEL
	Composition	Each gram of gel contains: Flurbiprofen……..0.05gm/g
	Diary No. Date of R& I & fee	Dy No. 14529 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792389 dated 06-03-2019
	Pharmacological Group	Anti-inflammatory preparations, non-steroids for topical use ATC Code M02AA19
	Type of Form	Form 5
	Finished Product Specification	BP, as stated by applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Relaxoen Gel E-Pharm Laboratories, A-40 S.I.T.E Super Highway North Karachi, Karachi
	GMP status	Last GMP inspection conducted on 10-07-2019

	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Finished product monograph is not available in BP, USP or JP. Provision of BP monograph of applied product or change in specifications of finished product along with prescribed fee 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 is required. • Change label claim to read as follows: "Each gram of gel contains: Flurbiprofen……..0.05gram", along with submission of requisite fee.
	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.** • **Latest GMP inspection report conducted within last three years.** • **Change label claim to read as follows:** **"Each gram of gel contains: Flurbiprofen……..0.05gram", along with submission of prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Provision of BP monograph of applied product or, in case of unavailability, change in specifications of finished product from BP to Manufacturer's Specifications along with prescribed fee.**	
666.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	Molyfax Plus Ointment
	Composition	Each gram ointment contains: Polymyxin B Sulfate……10,000 units Bacitracin Zinc…….500 units Lignocaine ……...4%
	Diary No. Date of R& I & fee	Dy No. 14600 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792390 dated 06-03-2019
	Pharmacological Group	Other antibiotics for topical use ATC Code D06AX05
	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.	Not confirmed
	Me-too status	Not available in combination with lignocaine
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. • 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.
	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 applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Latest GMP inspection report conducted within last three years.**	
667.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	BETA-BC CREAM
	Composition	Each gram of cream contains: Betamethasone(as dipropionate)USP…….0.5mg (0.05% w/w) Clotrimazole USP……10mg (1% w/w)
	Diary No. Date of R& I & fee	Dy No.14729 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792382 dated 06-03-2019
	Pharmacological Group	Antifungals for topical use ATC Code D01A
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lotrisone topical cream USFDA Approved
	Me-too status	Betazole Cream Xenon Pharamaceuticals (Pvt) Ltd., Lahore
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of separate dispensing facility for dispensing of steroidal materials is required
	Decision: Deferred for latest GMP inspection report conducted within last three years clearly mentioning availability of separate dispensing facility or otherwise, for dispensing of steroidal raw materials.	
668.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	BETA-D CREAM
	Composition	Not given
	Diary No. Date of R& I & fee	Dy No.16730 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792383 dated 06-03-2019
	Pharmacological Group	Corticosteroids, potent (group III) ATC Code D07AC01
	Type of Form	Form 5 not provided
	Finished Product Specification	Not stated
	Pack size & Demanded Price	Not stated
	Approval status of product in Reference Regulatory Authorities.	Not stated
	Me-too status	Not stated
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Complete application on Form 5 and all required undertakings duly signed and stamped by company's authorized representative are required.

		• Evidence of separate dispensing facility for dispensing of steroidal materials is required.
	Decision: Registration Board rejected the application is not submitted on Form 5.	
669.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	BREN GEL 10%
	Composition	Each gram of gel contains: Ibuprofen…….. 100mg/g
	Diary No. Date of R& I & fee	Dy No. 14595 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792385 dated 06-03-2019
	Pharmacological Group	Anti-inflammatory preparations, non-steroids for topical use ATC Code M02AA13
	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.	Fenbid Forte 10% Gel PL 10972/0082 MHRA Approved. However, the approved product contains 1mg of Benzyl alcohol per 100mg as excipient with known effect.
	Me-too status	Fynkoben Cream FYNK Pharmaceuticals, Lahore.
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Revision of master formulation according to composition given in MHRA along with relevant fee.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years.** • **Revision of master formulation according to composition given in MHRA along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**	
670.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	LIGAIN 5% OINTMENT
	Composition	Each gram of cream contains: Lidocaine(Lignocaine)……0.05gm/gm
	Diary No. Date of R& I & fee	Dy No. 14572 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789175 dated 07-03-2019
	Pharmacological Group	Local anaesthetic
	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.	Not confirmed
	Me-too status	Xyloaid 5% Ointment Reg. No. 23075
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Change label claim to read as follows:

		"Each gram of ointment contains: Lidocaine(Lignocaine)……0.05gm", along with submission of requisite fee. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required.
	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,** • **Change label claim to read as follows:** **"Each gram of ointment contains: Lidocaine(Lignocaine)……0.05gm", along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
671.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	FUDE-B CREAM
	Composition	Each gram cream contains: Fusidic acid……...20mg (2%) Betamethasone (as valerate)…….1mg
	Diary No. Date of R& I & fee	Dy No. 14596 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792386 dated 06-03-2019
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics ATC Code D07CC01
	Type of Form	Form 5
	Finished Product Specification	USP Specifications, as stated by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xemacort 20 mg/g + 1 mg/g cream PL 04569/1625 MHRA Approved
	Me-too status	Baxidin-B Cream Reg. No. 67597 Baxter Pharmaceuticals, A-1/A Scheme No. 33 Phase-I S.I.T.E. Super Highway Karachi., Karachi
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Form 5 and all required undertakings duly signed and stamped by company's authorized representative are required. • Finished product is not available in USP. Change of specifications from USP to Manufacturer's specifications along with relevant fee is required.
	Decision: Registration Board rejected the application since the application is not signed by company's representative and cannot be considered for evaluation.	
672.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	T-PAR tablet 75/650mg
	Composition	Each film coated tablet contains: Tramadol……..……75mg Acetaminophen……650mg
	Diary No. Date of R& I & fee	Dy No. 14590 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789194 dated 07-03-2019

	Pharmacological Group	Opioids in combination with non-opioid analgesics ATC Code N02AJ13
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available in film coating
	Me-too status	Tonoflex-P Forte Tablets 75mg/650mg Reg. No. 94798 SAMI Pharmaceuticals Pvt. Ltd.
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. • Applied formulation includes Tramadol 75mg, whereas formulation of product registered in DRAP and in USP includes Tramadol Hydrochloride 75mg. Change of acid/base form to salt form along with relevant fee is required.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Change of acid/base form of API to salt form as already registered by DRAP along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**	
673.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	FLAVO tablet 500mg
	Composition	Each film coated tablet contains: Micronized purified flavonoid fraction
	Diary No. Date of R& I & fee	Dy No. 14593 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789197 dated 07-03-2019
	Pharmacological Group	Vasoprotective
	Type of Form	Form 5
	Finished Product Specification	USP Specifications, as stated by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed as complete composition is not provided
	Me-too status	Not found as complete composition is not provided
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Master formulation describing quantities of actives and excipients along with the justification/role each ingredient. • Label claim does not include quantity of API. Label claim needs to be revised according to the master formulation.

		• Finished product is not available in USP. Change of specifications from USP to Manufacturer's specifications along with relevant fee 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 is required. • 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.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years.** • **Submission of master formulation describing quantities of actives and excipients along with the justification/role each ingredient.** • **Revision of label claim as per master formulation to include quantity of API.** • **Justification of submitted finished product specifications, since firm has claimed USP specifications whereas USP monograph is not available for applied formulation. In case of change from USP to Manufacturer's specifications, firm shall submit prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **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.**	
674.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	NARTIDAC tablet 1.5/5mg
	Composition	Each film coated modified release tablet contains: Indapamide……1.5mg Amlodipine (as besilate)……5mg
	Diary No. Date of R& I & fee	Dy No. 16725 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792381 dated 06-03-2019
	Pharmacological Group	Calcium channel blockers and diuretics ATC Code C08GA02
	Type of Form	Form 5
	Finished Product Specification	USP Specifications, as stated by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Natrilam 5 mg Tablets Reg. No. 90507 Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd., Lahore
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Finished product is not available in USP or any other pharmacopoeia. Change of specifications from USP to Manufacturer's specifications along with relevant fee 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 is required.

	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years.** • **Justification of submitted finished product specifications, since firm has claimed USP specifications whereas USP monograph is not available for applied formulation. In case of change from USP to Manufacturer's specifications, firm shall submit prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**	
675.	**Name and address of manufacturer / Applicant**	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	LORA-P CR 5mg/120mg tablet
	Composition	Each film coated controlled release tablet contains: Loratidine USP……..…5mg Pseudoephedrine Sulphate USP……..120mg
	Diary No. Date of R& I & fee	Dy No. 14573 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789176 dated 07-03-2019
	Pharmacological Group	Nasal decongestants for systemic use ATC Code R01BA52
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Claritin-D 12 hour extended release tablet Bayer Healthcare LLC USFDA Approved
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years. • Change of master formulation to include Loratidine is required along with requisite fee. • 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.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within last three years.** • **Change of master formulation to include Loratidine along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

Agenda of Mr. Ishtiaq

Case: Registration applications of local manufacturing of human drugs submitted on CTD format (New Section)

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 / 7 products)
iii. Dry powder suspension section (Cephalosporin) (1 molecule / 2 products)
iv. Tablet (Psychotropic)

676.	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	CIAXON 2 gm IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as Sodium……2 gm
	Pharmaceutical form of applied drug	Dry Powder for Injection
	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	Rocephin 2 gm IV Injection (USFDA Approved).
	For generic drugs (me-too status)	Oxidil 2 gm 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 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 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 PROVIDED BY THE APPLICANT				
	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. SX20180229 issued by CFDA valid till 05/06/2023.
	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
	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.#	Section	Observation
	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 both Drug substance & Drug Product manufacturer is required.
	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 drug substance(s) shall be submitted.
	3.2.S.4.4	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.
	3.2.S.5	Provide COA of reference standard which is actually used in the analysis of drug substance.
	3.2.P.1	Submit master formulation including theoretical fill weight per vial.
	3.2.P.2.2.1	Pharmaceutical equivalence of the applied drug shall be established with the innovator/reference product and results of all the quality tests of the developed formulation and the innovator / reference product shall be submitted. 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.
	3.2.P.3.5	Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.
	3.2.P.5.1	Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.
	3.2.P.5.2	Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.
	3.2.P.5.3	Provide standard and sample preparation method used in analytical method verification studies. 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.

	3.2.P.5.3	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.
	3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.
	3.2.P.8	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 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).

Decision of 322nd Meeting of Registration board: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr.#	Section	Observation	Response of firm
1.	**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 both Drug substance & Drug Product manufacturer is required.	Firm has submitted copies of the Drug substance specifications and analytical procedures
2.	**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 drug substance(s) shall be submitted.	Firm has submitted analytical method verification studies including specificity, accuracy and repeatability
3.	**3.2.S.4.4**	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.	The crystalanity test was not performed. However particulate matter test is not mentioned by USP for the raw material, instead it is for product. The drug substance manufacturer follows USP as well as Chinese Pharmacopoeia monograph for ceftriaxone sodium, So claims the assay limit of > 84 %. While being the drug product manufacturer we have followed the USP Monograph for ceftriaxone and USP specifies the limit NLT 79.5%. Moreover, the raw material manufacturer limits are strict in this regard so material that comply the manufacturer specifications will definitely meets the USP Specification.

4.	**3.2.S.5**	Provide COA of reference standard which is actually used in the analysis of drug substance.	Firm has submitted COA of reference standard.
5.	**3.2.P.1**	Submit master formulation including theoretical fill weight per vial.	Firm has Submitted master formulation
6.	**3.2.P.2.2.1**	• Pharmaceutical equivalence of the applied drug shall be established with the innovator/reference product and results of all the quality tests of the developed formulation and the innovator / reference product shall be submitted. • 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.	• Firm has provided Pharmaceutical equivalence studies against Rocephin Injection by performing following parameters appearance, identification, pH, clarity of solution and assay. However, firm has not provided batch details of innovator product.
7.	**3.2.P.3.5**	Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.	Firm has submitted revised process validation protocols
8.	**3.2.P.5.1**	Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.	No justification provided
9.	**3.2.P.5.2**	Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.	Firm has submitted new method for testing of finished drug product.
10.	**3.2.P.5.3**	Provide standard and sample preparation method used in analytical method verification studies. 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.	Firm has submitted standard and sample preparation method used in analytical method verification studies. Firm has submitted method verification studies.
11.	**3.2.P.5.3**	• 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.	• Firm has submitted revised method verification studies. The reason for area difference is that in verification studies the injection volume was different, that is deviation from USP method. So method is re-verified.
12.	**3.2.P.6**	Provide COA of reference standard actually used in the analysis of drug product.	Firm has provided COA of reference standard.
13.	**3.2.P.8**	• 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	• Firm has submitted In-use studies for drug products for 24 hours Complete stability data not submitted. The constituted solution was

		time point during the stability testing of each batch. • 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).	checked at every point of stability studies since the assay is performed after reconstituting the injection. So after reconstitution and before assay the injection was checked for particulate matter in injection or any foreign particle. At all points the results were satisfactory according to USP specified limits. However, justification not provided for water content test. Not 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.**

677.	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. 5860 Dated 03-03-2022
	Details of fee submitted	PKR 30,000/-: Dated 25-01-2022
	The proposed proprietary name / brand name	PENSEF 500mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cephradine as monohydrate…….500mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, First-generation cephalosporins.

	Reference to Finished product specifications	USP
	Proposed Pack size	1x12's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefradine 500mg Capsules (MHRA Approved).
	For generic drugs (me-too status)	Velosef 500 mg Capsule
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, 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 Cephradine as Monohydrate 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: 5°C ± 3°C for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% RH for 6 months Batches: (32051704109, 32051704110, 32051704111)
	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 Velosef 500 mg Capsule by Glaxosmithkline Pakistan Limited by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Velosef 500 mg Capsule by Glaxosmithkline

		Pakistan Limited 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 Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.		
API Lot No.	00203-08/110/2021		
Description of Pack (Container closure system)	Blister packof 2x6'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		
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.	The firm has submitted copy of GMP certificate of M/s Zhejiang Anglikang pharmaceutical Co. Ltd. China issued by China Food and Drug administration. It is valid till 30-08-2020.	
	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice (2021042801) specifying purchase of Cephradine compacted (100kg, Batch # 32052010034) attested by Assistant Director (I &E), Peshawar dated 18-05-2021.	
	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.#	Section	Observation	Response of firm
1.	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug	Copies of the Drug substance specifications and analytical procedures used for routine testing

		substance/ Active pharmaceutical ingredient by both drug substance & drug product manufacturer is required.	of the Drug substance/ Active pharmaceutical ingredient by both drug substance & drug product manufacturer have been 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 both compendial as well as non-compendial drug substance(s) shall be submitted.	Analytical method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug product manufacturer have been submitted
3.	3.2.S.4.4	The Submitted COA of Drug substance and drug product manufacturer does not include contents of cephalexin as recommended by USP (NMT 5.0%) The submitted COA from drug product manufacturer is not readable. Provide readable copy of COA.	Firm has stated that in the testing of Raw material the peak of Cephalexin is also present in the chromatogram, so the results of cephalexin can be calculated from Chromatogram. COA of batch no. 32052010034 has been submitted.
4	3.2.S.5	Provide COA of reference standards for both cephradine and cephalexin which is actually used in the analysis of drug substance including source and lot number.	Firm has provided in house working standard COA of Cephradine compacted of batch no. 32052010034
5.	3.2.S.7	The details of batches of stability study data of drug substance in module 3 are different from the bathes provided in module 2.	Firm has submitted following batches(32051704109, 32051704112, 32051704111)
6.	3.2.P.1	Submit master formulation including theoretical fill weight per bottle along with details of equivalency factor for cephradine. List all components of the dosage form , and their amount on a per unit basis (including overages, if any), the function of the components , and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications).	Submitted
7.	3.2.P.2.2.1	Justify why drug release studies /comparative Dissolution studies were not performed Against innovators product. Justify how same results are obtained for Pharmaceutical equivalence and CDP studies for both Cephradine 250mg and 500mg Capsule	Du to unavailability of innovator. CDP of both strengths are different. In dossier while compiling same CDP was attached for both strengths.
8.	3.2.P.2.2.4	Justify why the tests of reconstitution time , clarity and colour after reconstitution are included in this section. Moreover , flow chart of manufacturing also showed the process for dry powder for suspension.	Both reconstitution test and test for clarity of solution are for ceftriaxone injection, while drafting these test appeared in these section.
9.	3.2.P.3	A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	submitted

10.	3.2.P.5.1	The test for uniformity of dosage unit, deliverable volume and water determination are not added in specifications as recommended in USP monograph. Revise your specifications as per USP monograph along with submission of applicable fee. The assay limits mentioned in specifications are 90%-102% which are different from USP specifications (90%-125%)	Firm has submitted revised specifications. However requisite fee for change in specifications has not been submitted.
11.	3.2.P.5.2	Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing copy of USP monograph.	Submitted
12.	3.2.P.5.3	Provide standard and sample preparation method 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%, 1005 and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies while applied formulation is cephradine Capsules. The peak area of standard solution concenteration in analytical method verification studies is approximately 6609294 while the peak area of the standard solution of same concenteration is stability studies is 585429. Clarify the difference in Peak areas.	Submitted The mistake occurred while compiling the empazin tablet dossier and pansef sapsule dossier. The actual area is near about 585429 approx. Thee are difference s because of different in injection volume. The method was verified with actual injection volume.
13.	3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.	Firm has provided in house working standard COA of Cephradine compacted of batch no. 32052010034
14.	3.2.P.8	The results of batch analysis and stability data reflect that tests of uniformity of dosage units , water contents ,dissolution have not been performed throughout stability studies . Justify your stability study data without performance of tests recommended by Pharmacopoeia. Justify the addition of test of pH in stability studies of Cefadroxil capsule which is not present in USP monograph applied product.	The dissolution test was performed at each interval of accelerated and real time stability study. USP dissolution parameter were adopted and all the results were found within the specified limit. Firm has not provided revised stabillty data sheets. pH test was performed as an internal test. The pH test was performed by same method as that of cephradine raw material.

		Provide raw data sheets to justify the calculation of results for assay testing at each time point during the the stability testing of each batch. Submit copy of invoice for evidence of purchase of drug substance used in the development of analysis of each batch of drug product. Provide copy of BMR for the batches of drug product for which stability studies data is provided in Module 3 section 3.2P.8.3 Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. .	Raw data sheets submitted but chromatograms has not been submitted. Firm has submitted invoice no. 2021042801, dated 28-01-2021, specifying import of 100 kg Cephradine compacted import, duly attested by Assistant Director, DRAP. Submitted As our pharma is new licensee, and we have not came into production. now we have HPLC (Shimadzu 10 AT) which is not 21 CFR Compliance. However we commit that we will soon perform the stability studies on a 21 CFR compliance HPLC system

Decision of 322nd meeting of Registration Board: Deferred the case for following submissions:
Data of stability batches supported by attested respective documents like chromatograms, summary data sheets involving the performance of all pharmacopoeial tests.
Submission of the valid copy of GMP Certificate of Drug substance manufacturer.
Submission of fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

Decision of 322nd meeting of Registration Board	Response of firm
Data of stability batches supported by attested respective documents like chromatograms, summary data sheets involving the performance of all pharmacopoeial tests. Submission of the valid copy of GMP Certificate of Drug substance manufacturer. Submission of fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	Firm has submitted data of stability batches. Firm has submitted valid GMP Certificate of Drug substance manufacturer valid till 30-08-2025. Firm has submitted fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

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.**

678.	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. 5857 Dated 03-03-2022
	Details of fee submitted	PKR 30,000/-: Dated 25-01-2022
	The proposed proprietary name / brand name	PENSEF 125mg/5mL Dry Powder for Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml after reconstitution contains: Cephradine as Monohydrate 125mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, First-generation cephalosporins.
	Reference to Finished product specifications	USP
	Proposed Pack size	1x12’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed.
	For generic drugs (me-too status)	Velosef 125MG/5MLSuspension
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, 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 Cephradine as Monohydrate 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: (32052010037, 32052010038, 32052010039)
	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 Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.		
API Lot No.	32052010034		
Description of Pack (Container closure system)	60ml HDPE Bottle with embossed board unit carton UV coated.		
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	1000	1000	1000
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	28-05-2021	28-05-2021	28-05-2021
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.	ZJ20150108 Date:08-03-2020

	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of GMP certificate of M/s Zhejiang Anglikang pharmaceutical Co. Ltd. China issued by China Food and Drug administration. It is valid till 30-08-2020.
	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.#	Section	Observation	Response of firm
	1.5.9	Evidence of approval of applied formulation (Pensef 125mg/5ml Dry powder for suspension) in reference regulatory authorities adopted by Registration Board in 275th meeting shall be submitted.	Firm has not provided evidence. However, product was USFDA approved but discontinued.
	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 both Drug substance & Drug Product manufacturer are required.	Firm has submitted USP specifications and Monograph
	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 drug substance(s) shall be submitted.	Firm has submitted Method Verification studies report encompassing system suitability, Accuracy and recovery, Repaetabilty, intermediate precision and specificity.
	3.2.S.4.4	The submitted COAs from both drug substance and drug product manufacturer shows that the material used is of compacted nature. Justify the type of drug substance used in cephradine suspension since the same is used in Capsule dosage form. Provide readable copy of COA performed by M/s Alpenglow Pharmaceuticals.	Firm has submitted that Mistakenly the COA of compacted was submitted. The material used in dry suspension is of micronized nature. Firm has submitted COA
	3.2.S.5	Provide COA of reference standard which is actually used in the analysis of drug substance alongwith source and lot no.	Firm has submitted COA of in-house working standard for Cephradine (micronized) no. 0023/110/2021,
	3.2.P.1	Submit master formulation including theoretical fill weight per bottle alongwith details of equivalency factor for cephradine monohydrate.	Master formulation including theoretical fill weight per bottle alongwith details of equivalency factor for cephradine monohydrate submitted.
	3.2.P.2.2.1	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.	Firm has submitted Pharmaceutical equivalence studies against VELOSEF 250 mg mg/5ml powder for suspension Firm has submitted that compatibility studies involving the

		Justify the performance of pharmaceutical equivalence studies with Velosef 250mg / 5ml IV Dry powder injection while applied formulation is dry powder for suspension. Justify why drug release studies / comparative dissolution studies were not performed to justify your formulation development process.	reconstitution of Cephradine 250 mg/5ml dry suspension using purified water was performed. The Pharmaceutical equivalence studies were performed with velosef dry powder for suspension. This is typographic mistake that velosef injection is mentioned. As the cephradine suspension is formulated as per USP specifications, and neither USP does not defined the test for dissolution of product nor FDA suggests, so the dissolution is not considered in specification of finished product. However in the process of pharmaceutical development comparative dissolution was performed in three different medium under in-house set parameters.
	3.2.P.5.1	The test for uniformity of dosage unit, deliverable volume and water determination are not added in specifications as recommended in USP monograph. Revise your specifications as per USP monograph along with submission of applicable fee. The assay limits mentioned in specifications are 90% -102% which are different from USP specifications (90%-125%).	Firm has provided Revised specifications of finished product. However, fee for specification revision has not been provided. This is a typographic mistake. Actual limit is 90.0%-125.0%
	3.2.P.5.2	Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing copy of USP monograph.	Submitted
	3.2.P.5.3	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 test including the details of concentration of 80%, 100% and 120% solutions.	submitted
	3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.	Firm has provided COA of in house working standard of batch no. 0023/110/2021.
	3.2.P.8	The results of batch analysis and stability data reflect that tests of uniformity of dosage units, water contents, dissolution have not been performed throughout stability studies. Justify your stability study data without performance of tests recommended by pharmacopoeia. Justify the addition of test of pH in stability studies of cephradine capsule which is not present in USP monograph of applied product. 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 firm has submitted only raw data sheets at different testing time points. However, other information has not been provided.

		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. Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	

Decision of 322nd meeting of Registration Board: Deferred the case for following submissions:
Evidence of approval of applied formulation in reference regulatory authorities as decided by Registration Board in its 275th meeting.
Submission of valid GMP Certificate of Drug Substance manufacturer.
Data of stability batches supported by attested respective documents like chromatograms, summary data sheets involving the performance of all pharmacopoeial tests.
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.
Submission of fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

Decision of 322nd meeting of Registration Board	Response of firm
Evidence of approval of applied formulation in reference regulatory authorities as decided by Registration Board in its 275th meeting.	**Not submitted**
Submission of valid GMP Certificate of Drug Substance manufacturer.	
Data of stability batches supported by attested respective documents like chromatograms, summary data sheets involving the performance of all pharmacopoeial tests.	Submitted
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.	Submitted
Submission of fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	Firm has submitted fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021(650223749)

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.

Registration-II Section

Case No. 01: Decision of USFDA to Withdraw Approval of Makena (Hydroxyprogesterone Caproate Injection) and its Generics

On April, 06, 2023, U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

In 2011, FDA approved Makena to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. This accelerated approval was based on a trial that showed the drug reduced deliveries before 37 weeks of pregnancy, an intermediate clinical endpoint that FDA determined was reasonably likely to predict clinical benefit to the newborn.

As a condition of Makena's accelerated approval, the sponsor was required to conduct a confirmatory clinical trial to verify and describe the predicted clinical benefit to newborns. This trial, which was nearly four times larger than the trial that supported Makena's approval, did not show improvement in the health of the babies born to mothers who were treated with Makena. Makena and its generics (i.e., generic versions of Makena) are not shown to be effective for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Nor have Makena and its generics been shown to be effective for

any subgroup of this population, including in women at high risk of preterm birth. In addition, there are known risks associated with Makena. Accordingly, these drugs do not have benefits that outweigh their risks to patients.

Registration Board while considering the approval of Hydroxyprogesterone Injection in USFDA registered following drug products.

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer	Renewal Status
1.	096479	Nandrosol 250mg Injection Each ml contains: Hydroxyprogesterone caproate.....……250mg	Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore	Renewal is not yet due
2.	094205	Hygest Injection Each ml contains: Hydroxyprogesterone caproate.....……250mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is not yet due
3.	003531	Hydroxyprogesterone Injection Each ml contains: Hydroxyprogesterone caproate.....……250mg	M/s. Zafa Pharmaceutical, Karachi.	Renewal is valid
4.	030526	Globinan 2Ml Injection Hydroxy Progesterone Caproate…. 250mg	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
5.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
6.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate.....……250mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore	Renewal Not Submitted
7.	003746	HYDROXYPROGESTRONE INJECTION Each ml contains: Hydroxyprogesterone caproate.....……250mg	Haji Medicines, Rawalpindi	Renewal Not Submitted
8.	003833	HYDROXYPROGESTRONE Each ml contains: Hydroxyprogesterone caproate.....……250mg		Renewal Not Submitted

Following combination drug products containing Hydroxyprogesterone were also registered by the Registration Board.

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer	Renewal Status
1.	103324	Kevi Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Hansel Pharmaceuticals (Pvt) Ltd., Plot No 2 Pharma City 30-Km Multan Road Lahore. , Lahore	Renewal is not yet due
2.	084375	Contrex Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is valid
3.	077108	Z-Bron Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Pharma Health Pakistan (Pvt) Ltd.	Renewal is valid
4.	011155	VIO-DEPOT INJ HYDROXYPROGESTERONE CARPOATE 250MG QUESTRADIOL VALERATE 5MG SESAME OIL 693MG	Wilson's Pharmaceuticals	Renewal Not Submitted

5.	000798	GRAVIBINON INJECTION HYDROXY PROGESTERONE CAPROATE 250MG, , OESTRADIOL VALERATE IN OILY SOLUTION	Medipharm (Private) Limited,, 7-A, Gulberg II, Lahore, Lahore	Last renewal was submitted dated 02-10-2018

Sub-rule 10 (a) of Rule 30 of Drugs (L, R & A) Rules, 1976 narrates as under:

"(a) if that drug at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentors, to immediately withdraw the drug from the market in Pakistan or, as the case may be to impose similar restriction and to inform the registration Board within fourteen days of such an information having come to his knowledge and having taken the necessary action. The Registration Board after getting the said intimation shall take similar action for the same drug available from other sources within the shortest possible time;"

Decision:

Registration Board decided to: -

i. **Recall of Hydroxyprogesterone containing drug product under rule 30 (10) (a) of the Drugs (L, R &A) Rules, 1976 under the Drugs Act, 1976. QA&LT Division through field force, shall submit data of recalled product to Division of PE&R.**
ii. **Issue show-cause notice under section 7(11) (d) read with section 42 of Drug Act 1976/schedule VI of DRAP Act 2012 to all registration holders having valid registration of Hydroxyprogesterone containing drug products.**
iii. **Advised RRR Section to proceed for cancellation of registration for Hydroxyprogesterone containing drug product for which renewal was not submitted within due period of time.**

Post Registration-II Section

1. M/s Gray's Pharmaceuticals Rawat: Deferred Cases in 316th Meeting of Registration Board.

It is submitted M/s Grays Pharmaceuticals Plot No. 2 Street N-3 National Industrial Zone Rawat has requested for issuance letters of transfer of registration of below mentioned products registered in their name:

Sr. No.	Reg. No.	Brand Name	Composition
1.	044218	Graypime 1gm Injection	Each vial contains Cefepime (as HCl) …….1gm
2.	044219	Graypime 500gm Injection	Each vial contains Cefepime (as HCl) ……500gm
3.	044220	Solobect 1gm Injection	Each vial contains: Cefoperazone (as Sodium) ……0.5gm Sulbactum (as Sodium) ….0.5gm
4.	044221	Solobect 2gm Injection	Each vial contains: Cefoperazone (as Sodium) ……1gm Sulbactum (as Sodium) ….1gm
5.	044222	Cephagray 250mg Injection IM/IV	Each vial contains: Cephradine with L-Arginine……250mg
6.	044223	Cephagray 500mg Injection IM/IV	Each vial contains: Cephradine with L-Arginine……500mg
7.	044224	Cephagray 1g Injection IM/IV	Each vial contains: Cephradine with L-Arginine……1g
8.	031929	Medoxin 250mg Injection IM/IV	Each vail contains: Cefotaxime (as sodium)….250mg
9.	031930	Medoxin 500mg Injection IM/IV	Each vial contains: Cefotaxime (as sodium)….5000mg
10.	031931	Medoxin 1g Injection IM/IV	Each vial contains: Cefotaxime (as sodium)….1g
11.	031932	Ne-Zone 250mg Injection IM/IV	Each vial contains: Ceftriaxone (as Sodium)….250mg
12.	031933	Ne-Zone 500mg Injection IM/IV	Each vial contains:

			Ceftriaxone (as Sodium)….500mg
13.	031934	Ne-Zone 1g Injection IM/IV	Each vial contains: Ceftriaxone (as Sodium) …. 1g
14.	063347	Diclogray Injection	Each 3ml contains; Diclofenac sodium …..75mg
15.	063342	Inflacid Injection	Each ml contains Piroxicam …..20mg

The firm has submitted following documents:

a. Copy of minutes of 233rd meeting of Registration Board.
b. Copies of registration letters
c. Copies of approvals of contract manufacturing permissions
d. Submission of fee for transfer of registration
e. Copies of evidence of submission of renewal applications

2. Background of the case is that below mentioned products were registered in name of M/s Gray's Pharmaceuticals Plot No. 442, Street No. 7, I-9/2 Islamabad. Product details with onward approvals are reflected in column VII below:

Sr. No.	Reg. No.	Brand Name	Date of Reg.	Fee submitted	Last renewal details	Remarks:
I	II	III	IV	V	VI	VII
1.	044218	Graypime 1gm Injection Each vial contains Cefepime (as HCl) …….1gm (USP Specifications) **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.8000/-dated 07.05.2012 Rs.12000/- dated: 18.12.2013	29.03.2021 Rs. 10000/-	• Initially registered for contract mfg from M/s Ipram Pharmaceuticals Rawat vide letter No. F.3-5/2006 Reg-II South (M-199) dated 05.10.2006. • Approval for extension in contract manufacturing from M/s Global Pharmaceuticals Islamabad vide letter No. F.1-62/2006 Reg-II South dated 19.07.2008 valid till 30.06.2010 • Interim extension in contract mfg permission to all manufacturers vide approval No. 6-17/2006-Reg-II (Pt. II) dated 30.06.2010 valid till 31.12.2010 & dated 07.06.2011 till 31.08.2011 & dated 21.09.2011 valid till 31.10.2011
2.	044219	Graypime 500gm Injection Each vial contains Cefepime (as HCl) ……500gm (USP Specifications) **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	29.03.2021 Rs. 10000/-	
3.	044220	Solobect 1gm Injection Each vial contains: Cefoperazone (as Sodium) ……0.5gm Sulbactum (as Sodium) …….0.5gm (USP Specifications) **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	29.03.2021 Rs. 10000/-	
4.	044221	Solobect 2gm Injection Each vial contains: Cefoperazone (as Sodium) ……1gm Sulbactum (as Sodium) …….1gm (USP Specifications) **Contract manufacturer:**	05.10.2006	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	29.03.2021 Rs. 10000/-	

		M/s Global Pharmaceuticals Islamabad.				
5.	044222	Cephagray 250mg Injection IM/IV Each vial contains: Cephradine with L-Arginine……250mg **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.20000/- dated 02.09.2016	29.03.2021 Rs. 10000/-	• Initially registered for contract mfg from M/s Ipram Pharmaceuticals Rawat vide letter No. F.3-5/2006 Reg-II South (M-199) dated 05.10.2006. • Approval for extension in contract manufacturing from M/s Global Pharmaceuticals Islamabad vide letter No. F.1-62/2006 Reg-II South dated 2304.2009 valid till 30.06.2010 • Interim extension in contract mfg permission to all manufacturers vide approval No. 6-17/2006-Reg-II (Pt. II) dated 30.06.2010 valid till 31.12.2010 & dated 07.06.2011 till 31.08.2011 & dated 21.09.2011 valid till 31.10.2011
6.	044223	Cephagray 500mg Injection IM/IV Each vial contains: Cephradine with L-Arginine……500mg **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.20,000/- dated 02.09.2016	29.03.2021 Rs. 10000/-	
7.	044224	Cephagray 1g Injection IM/IV Each vial contains: Cephradine with L-Arginine……1g **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.20,000/- dated 02.09.2016	29.03.2021 Rs. 10000/-	
8.	031929	Medoxin 250mg Injection IM/IV Each vail contains: Cefotaxime (as sodium)….250mg **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	• Initially registered for contract mfg from M/s Vision Pharmaceuticals Islamabad vide letter No. F.3-3/2003 Reg-II (M-179) dated 10.12.2003. • Approval for extension in contract manufacturing from M/s Global Pharmaceuticals Islamabad vide letter No. F.1-62/2006 Reg-II South dated 08.11.2008. • Interim extension in contract mfg permission to all manufacturers vide approval No. 6-17/2006-Reg-II (Pt. II) dated 30.06.2010 valid till 31.12.2010 & dated 07.06.2011 till 31.08.2011 & dated 21.09.2011 valid till 31.10.2011
9.	031930	Medoxin 500mg Injection IM/IV Each vail contains: Cefotaxime (as sodium)….500mg **Contract manufacturer:** Vision Pharmaceuticals Islamabad	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	
10.	031931	Medoxin 1g Injection IM/IV Each vail contains: Cefotaxime (as sodium)….1gmg **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	
11.	031932	Ne-Zone 250mg Injection IM/IV Each vial contains: Ceftriaxone (as Sodium)…250mg **Contract manufacturer:**	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	

		M/s Global Pharmaceuticals Islamabad.				
12.	031933	Ne-Zone 500mg Injection IM/IV Each vial contains: Ceftriaxone (as Sodium)…500mg **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	
13.	031934	Ne-Zone 1g Injection IM/IV Each vial contains: Ceftriaxone (as Sodium) …1g **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	
14.	063347	Diclogray Injection Each 3ml contains; Diclofenac sodium….75mg **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	10.06.2010	Rs. 20,000/- dated 02.09.2016	16.06.2020 Rs. 10,000/-	• Both products were registered initially to be manufactured by M/s Global Pharmaceuticals vide Reg letters dated 08th & 10th June, 2010. These permissions were valid till 30.06.2010. • Interim extension in contract mfg permission to all manufacturers were granted multiple times which were valid till 31.10.2011.
15.	063342	Inflacid 20mg Injection Each ml contains; Piroxicam…..20mg **Contract manufacturer:** M/s Global Pharmaceuticals Islamabad.	08.06.2010	Rs. 20,000/- dated 16.11.2015	16.06.2020 Rs. 10,000/-	

2. The firm on 10.10.2011 requested for transfer of registration of above products from existing facility i.e. M/s Grays Pharmaceuticals Plot No. 442 Street No. 7 Sect I-9/s2 Industrial Area Islamabad to their new licensed manufacturing facility i.e. M/s Grays Pharmaceuticals Plot No. 2 Street N-3 National Industrial Zone Rawat, which was granted DML vide approval No. 1-7/2008-Lic dated 22.06.2008. Accordingly, the request of the firm was considered in 233rd meeting of Registration Board held on 15.06.2012 wherein the Board decided to accede the request of for transfer of registrations to M/s Grays Pharmaceuticals Rawat from M/s Grays Pharmaceuticals Islamabad subject to fulfillment of latest fee requirements and confirmation of sections. As per decision of the Board the firm submitted the requisite fee which is reflected in column V above. However, the letter of transfer of registration to new facility couldn't be issued.

3. The request of the firm for issuance of transfer letter as per decision of 233rd meeting of Registration Board was discussed in the 316th meeting of the Board held on 15-18th March 2022 firm wherein it was deferred for submission of evidence regarding submission of applications for extension in contract manufacturing permission up to year 2012 and subsequent renewals after year 2012.

4. The last renewal submission evidence details are recorded in the last column VI above as required by the Board in 316th meeting. Hence as per aforementioned renewal submissions, the renewal application for products at Sr. No. 1-7 are within time but the renewal submission for products at Sr. No. 8-15 are submitted after due date but within one year, therefore differential fee is required under SRO 1005(I)/2017.

Decision of 327th meeting of Registration Board:

The Board deliberated the matter at length. Considering the facts narrated above, the Board decided to cancel the above registrations in name of existing facility i.e., M/s Gray's Pharmaceuticals, Plot No. 442, Street No. 7, Sector I-9/2, Industrial Area Islamabad (DML No. 000518) and grant them in name of new licensed manufacturing facility i.e M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone Rawat (DML No. 000518)

by way of self manufacturing, subject to confirmation of renewal status under Rule 27 of the Drugs (LR&A) Rules 1976 amended vide SRO 1005(I)/2017 dated 05.10.2017. The firm shall also submit the fee if required under the afore said provisions.

Export Facilitation Desk

Case No.01: Registration of Drug (s) of M/s Swiss Pharmaceuticals (Pvt.) Ltd, A/159, S.I.T.E. Super Highway, Karachi 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.	Form 5;
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 renewal of DML dated 30-12-2014
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 06-07-2021
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.	**Vonzap 10/100mg Tablet** Each delayed release tablet contains: Aspirin.....100mg Vonoprazan fumarate eq to vonoprazan.....10mg	Purchase order from Sri Lanka Cabpirin film coated tablet are PMDA Japan approved. Firm has applied delayed release tablet.	Dy. No. 166(09.03.2023) Rs.75,000/- (16.12.2022)

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.

Case No.02: Registration of Drug (s) of M/s Fast Pharmaceuticals (Pvt.) Ltd, Plot No. 55, Street No. S-4, National Industrial Zone, 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.	Form 5;
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. Nil dated 29-04-2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 28-02-2022
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.	**Premac-N 75mg/1500mcg/10mg Tablets** Each film coated tablet contains: Pregablin (SR).....75mg Methycobalamin.....1500mcg Nortriptyline (as HCl).....10mg	Purchase order from Afghanistan	Dy. No. 183(10.03.2023) Rs.75,000/- (07.03.2023)
2.	**Minalin 75mg/1500mcg Tablets** Each film coated tablet contains: Pregabalin (SR).....75mg Methycobalamin.....1500mcg	Purchase order from Afghanistan	Dy. No. 198(15.03.2023) Rs.75,000/- (28.02.2023)
3.	**Diser 100mg/20mg Tablets** Each modified release tablet contains: Diclofenac sodium (as enteric coated core).....100mg Serratiopeptidase (as immediate release coat).....20mg	Purchase order from Afghanistan	Dy. No. 199(15.03.2023) Rs.75,000/- (07.03.2023)
4.	**Diser 50mg/10mg Tablets** Each modified release tablet contains: Diclofenac sodium (as enteric coated core)..50mg Serratiopeptidase (as immediate release coat).....10mg	Purchase order from Afghanistan	Dy. No. 200(15.03.2023) Rs.75,000/- (07.03.2023)
5.	**Apser 100mg/325mg/10mg Tablets** Each tablet contains: Aceclofenac.....100mg Paracetamol.....325mg Serratiopeptidase.....10mg	Purchase order from Afghanistan	Dy. No. 201(15.03.2023) Rs.75,000/- (07.03.2023)

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.

Case No.03: Registration of Drug (s) of M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar, 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 cGMP dated 10-12-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 10-12-2020
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	**Bio-Alaxin Suspension** Each 80ml of reconstituted suspension contains: Dihydroartemisinin.....80mg Piperaquine Phosphate.....640mg	Purchase order from Myanmar	Dy. No. 8869/22 (24.01.2023) Rs.75,000/- (11.01.2023)

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.

Case No.04: Registration of Drug (s) of M/s Rock Pharmaceuticals Laboratories (Pvt.) Ltd, Plot No. 134-B & 135-B, Nowshera Industrial Estate Risalpur, 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 3-1/98-Lic dated 15-11-2021
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 22-11-2022
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	**New Veribion Tablet** Each film coated tablet contains: Thiamine mononitrate U.S.P.....10mg Pyridoxine Hydrochloride U.S.P.....3mg Cyanocobalamin U.S.P.....15mcg Niacinamide USP.....45mg Calcium Pantothenate.....5mg	Purchase order from Nigeria	Dy. No. 238/23 (30.03.2023) Rs.75,000/- (22.03.2023)

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.

Case No.05: Registration of Drug (s) of M/s Nabi Qasim Industries (Pvt.) Ltd, 17/24, Korangi Industrial Area, Karachi, 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 2-20/85-Lic dated 27-04-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 27-05-2022
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
Remarks: Suxamethonium chloride 100 mg/2 ml is approved by MHRA of UK as liquid injection.	

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	**Succinab Lyophilized Powder for solution for I.M / I.V Injection 200mg** Each vial contains: Suxamethonium chloride BP.....200mg	Purchase order from Uganda	Dy. No. 239/23 (30.03.2023) Rs. 75,000/- (13.03.2023)
2	**Succinab Lyophilized Powder for solution for I.M / I.V Injection 100mg**	Purchase order from Uganda	Dy. No. 240/23 (30.03.2023) Rs. 75,000/- (13.03.2023)

	Each vial contains: Suxamethonium chloride BP.....100mg		

Decision: Registration board while considering the purchase order from the importing country i.e., Uganda decided to approve the applied products of Succinab Lyophilized Powder (Suxamethonium chloride) for solution for I.M / I.V Injection 200mg & Succinab Lyophilized Powder (Suxamethonium chloride) for solution for I.M / I.V Injection 100mg for export only for Uganda.

Case No.06: Registration of Drug (s) of M/s Sami Pharmaceuticals (Pvt.) Ltd, F-95, Off Hub River Road, S.I.T.E. Karachi, 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.	Form 5;
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 2-9/2007-Lic dated 22-06-2018
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 17-11-2022
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 are given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1	**PREGNO NEW MOM Tablets** Each film coated tablet contains: Hydrolyzed Marine Collagen….....100 mg Silica……..…..…10 mg Citrus Bioflavonoids…….....….……7.5 mg Co-Q10……..……5 mg Grape Seed Extract…….....……7.5 mg L-Methionine…….....……..……15 mg L-Cysteine…….....……. …..…….15 mg Beta Carotene…….....……..….1 mg VitaminD3…….....…...5mcg (200 IU) Vitamin E…….....……...20 mg α-TE Vitamin C….....40 mg Thiamine (Vitamin B1)…….....……4 mg Riboflavin (Vitamin B2)…….....……..…2 mg Niacin (Vitamin B3)…….....…….9 mg NE Vitamin B6……...……4 mg Folic Acid……..…...…….200 mcg Vitamin B12……....……10 mcg Biotin……..……..……75 mcg Pantothenic Acid…….....……20mg Calcium……...…… 200 mg Magnesium…….....…….37.5 mg Iron…….…….….....7 mg Zinc……...……...7.5 mg Copper…….....…….500 mcg Manganese……..….....……0.25 mg Selenium…….....…….50 mcg Chromium…….....……20 mcg Iodine……...……...75 mcg	Purchase order from Afghanistan Similar product of Vitabiotic UK is enlisted by H&OTC Division as imported product.	Dy. No. 241/23 (30.03.2023) Rs. 75,000/- (07.11.2022)
2	**PREGNO COMPLETE Tablets** Each film coated tablet contains: Vitamin D3……..…10 mcg (400IU) Vitamin E……4mg α-TE Vitamin K…….....……70mcg Vitamin C…….....……70mg Thiamin (Vitamin B1)…….....…….3mg Riboflavin (Vitamin B2)….....……2mg	Purchase order from Afghanistan Similar product of Vitabiotic UK is enlisted by H&OTC Division as imported product.	Dy. No. 242/23 (30.03.2023) Rs. 75,000/- (07.11.2022)

	Niacin (Vitamin B3)…….....…20mg NE Vitamin B6…….....……10mg Folic Acid…….....……400mcg Vitamin B12…….....……6mcg Biotin…….....……..150mcg Pantothenic Acid…….....…6mg Magnesium…….....……150mg Iron…….....……17mg Zinc…….....……15mg Copper…….....……1000 mcg Selenium …….....……30mcg Iodine …….....……l50mcg Beta Carotene…….....….2mg		
3	**PREGNO PRE-CONCEPTION Tablets** Each film coated tablet contains: L-Arginine…….....…….100mg Inositol…….....….50mg N-Acetyl Cysteine …….....……50mg Beta Carotene…….....…3mg Vitamin D_3 …….....….15mcg (600 IU) Vitamin E …….....…..4mg α-TE Vitamin C …….....90mg Thiamin (Vitamin B1) …….....8mg Riboflavin (Vitamin B2) …….....5mg Niacin (Vitamin B3)…….....20mg Vitamin B6 …….....……10mg Folic Acid …….....….400mcg Vitamin B12 …….....……20mcg Biotin …….....150mcg Pantothenic Acid …….....…6mg Magnesium …….....60mg Iron …….....14 mg Zinc …….....…….. 15mg Copper …….....… 1000mcg Selenium…….....…50mcg Iodine …….....50mcg	Purchase order from Afghanistan Similar product of Vitabiotic UK is enlisted by H&OTC Division as imported product.	Dy. No. 243/23 (30.03.2023) Rs. 75,000/- (04.11.2022)
4	**OSTIFLEX Tablets** Each film coated tablet contains: Glucosamine Sulphate KCl …….....250 mg Chondroitin Sulphate …….....….100 mg Ginger Root equivalent to (from extract)…...25mg Vitamin D3……....8.33 mcg (333.2 IU) Vitamin C…….....……..26.66 mg Calcium…….....…..266.66mg Magnesium…….....…….50mg Zinc…….....…..5 mg Copper…….....……..333.33 mcg Manganese…….....…….0.16mg Selenium…….....16.66mcg	Purchase order from Afghanistan Similar product of Vitabiotic UK is enlisted by H&OTC Division as imported product.	Dy. No. 244/23 (30.03.2023) Rs. 75,000/- (04.11.2022)

Decision: The Board deliberated the matter and decided that the firm shall apply in division of Health & OTC for export enlistment of their products.

Case No. 01: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following veterinary products approved in 291st meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S. No.	Name of Importer/ Manufacturer	Name of Drug/ Composition & meeting number	Panel of Inspector(s)/ Date of inspection
1.	M/s. Uranus Bio-Tech Private Limited. Office # 112, 1st Floor, Arooj Arcade, F10 Markaz, Islamabad, Pakistan **Manufacturer**:- M/s. Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Chan gzhou Road, Rongchang District, Chongqing, China.	**(i)** Albentong Sus 10 Oral Suspension Each ml contains:- Albendazole ……100mg (ii) Ivertong 1% Injection Each ml contains: Ivermectin ……..…10mg (iii) Flortong 30 Injection Each ml contains: Florfenicol ……..…300mg **(M-291)**	(i)Mr. Abdullah Abro, Deputy Director (MD&MC), DRAP, Islamabad. (ii)Malik Muhammad Asad, Deputy Director (Pharmacy Services), DRAP, Islamabad. **16h & 20th December, 2022**

Accordingly, an inspection was carried out by inspection panel dated 16h & 20th December, 2022 and final remarks of the panel are as under:-

Conclusion:

Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the firm has basic systems to manufacture veterinary drugs and appeared to comply the GMP requirements. Hence, the panel recommends that the Registration Board may grant the registration of applied products namely Albentong Sus 10 Oral Suspension (Albendazole …100mg) in 100ml plastic bottle, Flortong 30 Injection (Florfenicol ……300mg) in 100ml vial & Ivertong 1% Injection (Ivermectin…..10mg) in 10ml vial to M/s. Uranus Bio-Tech Private Limited, Islamabad. However, the panel strongly recommends on-site inspection in order to verify/ascertain the Good Manufacturing Practices (GMP) of the firm **within one year** as virtual inspection can never replace/in-person inspection.

Decision: **Decision: Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendations. The division shall process the case before issuance of minutes of the meeting.**

Case No. 02: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following veterinary products approved in 308th meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug/ Composition/	Panel of Inspector(s)/ Date of inspection

1.	M/s. Medicinia Corporation, 234, Sunny Plaza, Hasrat Mohani Road, Karachi. / Manufacturer & Marketing Authorization Holder:- M/s. Reyoung Pharmaceutical Co., Ltd., No.1, Ruiyang Road, Yiyuan County, Shandong Province, China.	**(i)** Amoclave Tablet 375mg Each film coated tablet contains:- Amoxicillin as Trihydrate…250mg Potassium Clavulanate as Clavulanic Acid……...125mg **(ii)** Amoclave Tablet 625mg Each film coated tablet contains:- Amoxicillin as Trihydrate……500mg Potassium Clavulanate as Clavulanic Acid……...……..125mg **(iii)** Amoclave Tablet 1000mg Each film coated tablet contains:- Amoxicillin as Trihydrate……..875mg Clavulanic Acid as Potassium Clavulanate ……..125mg **(M-308)**	(i)Mr. Abdullah Abro, Deputy Director (Controlled Drugs), DRAP, Islamabad. (ii)Mr. Muhammad Kashif, Deputy Director (Biological), DRAP, Islamabad. **13h & 14th February, 2023**

Accordingly, an inspection was carried out by inspection panel dated 13h & 14th February, 2023 and final remarks of the panel are as under:-

Conclusion & Recommendations:

Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the firm has basic systems to manufacture tablets and appeared to comply the cGMP requirements. Hence, the panel recommends that the registration of the applied products namely registration of applied products namely Amoclave Tablet (375mg,625 and 1000mg) may be granted to M/s. Medicinia Corporation, 234, Sunny Plaza, Hasrat Mohani Road, Karachi Karachi,

However, the panel strongly recommends on-site inspection in order to verify/ascertain the Good Manufacturing Practices (GMP) of the firm **within one year** as virtual inspection can never replace/in-person inspection.

Decision: Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendations. The division shall process the case before issuance of minutes of the meeting

Case No. 03: Request of M/s Selmore Pharmaceuticals Pvt. Ltd. for grant pack size of Redycef RTU Injection (Ceftiofur as hydrochloride):

2.	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 of 323rd meeting: Approved with innovator's specifications.	

Remarks: - Firm submitted 10ml pack sizes of same formulation of M/s. Nawan Laboratories (Pvt) Ltd., Karachi & M/s. S.J & G Fazul Elahi (Pvt) Ltd., Karachi.

M/s Selmore requested for grant of 10ml or 20ml as already granted (Reg. 063704, EXCEFUR INJECTION) to M/s. S.J & G Fazul Elahi (Pvt) Ltd., Karachi.

Decision: Registration Board deliberated the matter in detail and decided as under:

i. **Acceeded to the request of M/s Selmore Pharmaceuticals for grant of 20ml pack size and firm will submit full fee for change in pack size.**

ii. **Registration Board directed to Additional Director Karachi for confirmation of Ceftiofur 10ml Injection approval and manufacturing of Ceftiofur 10ml Injection of both firms i.e. M/s. Nawan Laboratories (Pvt) Ltd., Karachi & M/s. S.J & G Fazul Elahi (Pvt) Ltd., Karachi and submit the report to Chairman Registration Board/Director PE&R Division.**

Import & Vet-II Section

Case No: 01 REQUEST OF M/S AMTUL PHARMACEUTICALS, LAHORE REGISTRATION OF DRUGS (OMULCER 40MG INJECTION) UNDER THE DRUGS ACT, 1976.

The subject case was discussed in 320th meeting of Registration Board as under: -

Registration Board in its 261st meeting approved the following product of M/s. Amtul Pharmaceuticals, Lahore as per decision mentioned alongside each;

Importer M/s. Amtul Pharmaceuticals, 251-Sikandar Block Allama Iqbal Town, Lahore Manufacturer: M/s Reyoung Pharmaceutical Co.No.6, Erlangshan Road,Yiyuan County,Shandong Province, P.R. China. Priority # 85	Omulcer 40mg Injection Each vial of lyophilized powder contains:- Omeprazole Sodium 40mg Proton Pump Inhibitior Specifications:- Manufacturer	Pack size one vial Rs. 750/-	Approved as per Import Policy for Finished Drugs.

Now, M/s AMB HK Enterprises (Pvt) Ltd, Lahore has submitted request for registration of above product on their name and submitted following documents: -

- Original cancellation letter from REYOUNGE to M/s Amtul Pharmaceuticals, Lahore.
- Original agreement of REYOUNGE with M/s AMB HK Enterprises (Pvt) Ltd, Lahore.
- Original CoPP for Omeprazole 40mg Injection.

In view of above, a letter vide No.F.1-8/2020-I&V-II/Human Import dated 31st May, 2022 & reminder for the same dated 24th August, 2022 was conveyed to the firm and advised to submit fresh sole agency agreement letter in your name from product license holder and no reply from the M/s Amtul Pharmaceuticals, Lahore received.

Decision M-320: Registration Board considered the case and decided to issue a reminder to M/s. Amtul Pharmaceuticals, Lahore for submission of fresh sole agency agreement letter in their name form product license holder.

Proceedings of 327th meeting: The Board was apprised that M/s Amtul Pharmaceuticals had not submitted requisite documents as per decision of 261st meeting of Registration Board wherein the application was decided as "Approved as per Import Policy for Finished Drugs". The Board was further apprised that a reminder was issued to M/s Amtul Pharmaceuticals for submission of fresh sole agency agreement letter in their name from product license holder as per decision of 320th meeting of Board but

till date the firm has failed to submit required documents.

Decision: Registration Board while considering the above cited facts decided to withdraw the approval of 261st meeting in name of M/s. Amtul Pharmaceuticals, 251-Sikandar Block Allama Iqbal Town, Lahore for the "Omulcer 40mg Injection" and directed the I&V-II section for evaluation of M/s AMB HK Enterprises (Pvt) Ltd, Lahore application.

Case No: 02 M/S SANOFI-AVENTIS PAKISTAN REQUESTED FOR EXTENSION IN EXEMPTION FROM LABELING TEXT ON – GLUCANTIME 1.5G/5ML SOLUTION FOR INJECTION (REG. NO.088889)

M/s Sanofi-aventis Pakistan Limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi has requested that subject product is being manufactured and primarily packaged in large volume at the source point from where it will be exported / distributed to different countries as per their needs.

In light of the above, the firm requested for extension in labeling exemption of the said product and product import in Standard Export Packs and **locally print the Registration Number, Maximum Retail Price and Urdu Text on the packs once imported** at their licensed premises i.e. M/s Sanofi-aventis Pakistan Limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi (Drug Manufacturing License No.000007 by way of formulation)

Previously competent authority has granted permission on 15th March, 2021on the same subject mentioned as above.

Firm has submitted following supporting documents: -

1. A requisite fee Rs.10,000/-.
2. Copy of registration letter (issued on 17th May, 2018)
3. Copy of previous approval for Urdu labeling exemption.
4. SOP's for "Control of repacking operations"
5. An undertaking.

Decision: Registration Board acceded to the request of firm for extension in labeling exemption of the GLUCANTIME 1.5G/5ML SOLUTION FOR INJECTION (REG. NO.088889) to be imported in Standard Export Packs and locally print the Registration Number, Maximum Retail Price and Urdu Text on the packs once imported at their licensed premises i.e. M/s Sanofi-aventis Pakistan Limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi (Drug Manufacturing License No.000007 by way of formulation) to comply with the requirements as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two (02) year only. The firm shall submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

Case No. 1 Renewal applications referred to Registration Board by Renewal Sub Committee

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/s. Medera Pharmaceuticals (Pvt) Ltd.,Plot No.2, Street N-4 National Industrial Zone Rawat.					
1.	087360	Tazonem Injection 2g/250mg Each vial contains Piperacillin (as sodium) ….. 2gm Tazobactam (as sodium) ….250 mg (USP Specifications) **Contract Manufacturer:** M/s. Global Pharmaceuticals (Pvt) Ltd, Plot No.22-23, Industrial Triangle Kahuta Road, Islamabad.	03/01/2018	Dy. No.246 dated 03/01/2023 Rs.75000/- **Dy. No. 8390 dated 27.03.2023 Rs. 75000/-**	Renewal is granted w.e.f 03.01.2023 to 02.01.2028 .
2.	087359	Tazonem Injection 4g/500mg Each vial contains Piperacillin (as sodium) …4 gm Tazobactam (as sodium) …500 mg (USP specifications) **Contract Manufacturer:** M/s. Global Pharmaceuticals (Pvt) Ltd, Plot No.22-23, Industrial Triangle Kahuta Road, Islamabad.	03/01/2018	Dy. No.246 dated 03/01/2023 Rs.75000/- **Dy. No. 8390 dated 27.03.2023 Rs. 75000/-**	Renewal is granted w.e.f 03.01.2023 to 02.01.2028.
Remarks: The application was deferred in 8th meeting of Renewal Sub Committee for submission of differential fee Rs. 75000/- as renewal application is submitted after due date but within sixty days. The firm has now submitted the fee which is recorded above. Decision of the Board is mentioned against each case.					
M/s. Helix Pharma (Pvt) Ltd., A/56 SITE Mangopir Karachi.(DML No.000030)					
3.	028931	Tycef Capsule Each capsule contains: Cefixime USP….400mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	13/08/2002 Approval of contract Mfg: 24.11.2020 Valid till: **23.03.2022**	Rs: 10000/- dated 25.04.2022 Rs: 75000/- dated 25.04.2022 Rs.75000/- dated 29.07.2022	Deferred for opinion of Legal Affairs Division.
4.	028165	Tycef Paediatric Suspension Each 5ml contains: Cefixime USP….100mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	10/08/2002 Approval of contract Mfg: 24.11.2020 Valid till: **23.03.2022**	Rs: 10000/- dated 25.04.2022 Rs: 75000/- dated 25.04.2022 Rs.75000/- dated 29.07.2022	Deferred for opinion of Legal Affairs Division.

5.	048552	Tycef DS Suspension Each 5ml contains: Cefixime Trihydrate eq. to Cefixime….200mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	20/03/2008 Approval of contract Mfg: 24.11.2020 Valid till: **23.03.2022**	Rs: 10000/- dated 25.04.2022 Rs: 75000/- dated 25.04.2022 Rs.75000/- dated 29.07.2022	Deferred for opinion of Legal Affairs Division.

Remarks of RRR section in 8th Sub Committee:

The firm was given an approval of contract manufacturing from M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi for period of sixteen months i.e. till 23.03.2022 vide DRAP approval F.296-RB/2020 (PR-I) dated 24.11.2020 with the advice to submit quarterly progress on the activities undertaken by the firm in 296th meeting. Details are as under:

Phase 1: Renovation of general packaging area (tablets and capsules) will be completed by Dec-2020
Phase II: Renovation of blistering, coating &encapsulation will be completed by May 2021.
Phase III: Renovation of Dry Suspension, blending, granulation and packaging will be completed by November 2021
Phase IV: Renovation of liquid manufacturing, filling and packing will be completed by March 2022.
Phase V: Renovation of oral cephalosporin (capsule and dry powder suspension) will be completed by Feb,2022.

However instead of submitting the progress report the firm has submitted extension application. GMP inspection conducted by area FID dated 29.06.2022 wherein the GMP was rated as GOOD. Section approval letters vide letter No.F.2-1/2003-Lic Vol-II dated 21st June, 2021 indicating Dry Powder Suspension (Cephalosporin).

Decision of Renewal Sub Committee and Reply:

The application was deferred in 8th meeting of Renewal Sub Committee for submission of progress report as per undertaking in 296th meeting of Registration Board. In response to the above decision of the Committee the firm submitted reply vide Dy. No. 8391 dated 27.03.2023 wherein they have submitted that we have applied for withdrawal of Cephalosporin section due to non-feasibility for manufacturing of cephalosporin registered products & DRAP–Licensing section issued letter No. F.2-20/84-Lic (Vol-V), dated:23rd Oct, 2020 for withdrawal of Cephalosporin section is enclosed herewith for your kind perusal. Initially we have applied for contract manufacturing for our above registered products on basis of renovation /upgrade Cephalosporin area but later on we have withdrawn Cephalosporin section as mentioned above. Kindly consider our submitted application for renewal of Contract manufacturing along with fee of our registered Cephalosporin products & grant us the Contract Manufacturing for 05 years at your earliest on basis of withdrawal of Cephalosporin area.

Decision of the Board is mentioned against each case.

M/s. Amgomed Office No.04, 1st Floor, Ghousia Plaza Main Jinnah Blue Area Islamabad.

6.	053821	Amgozole infusion 40mg Each vial contains: Omeprazole as sodium……...40mg **Manufacturer:** M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad.	21.03.2009 Transfer of reg. from Import to local: **19.01.2015**	Rs. 50000/- dated; 18.03.2020 Dy. No. 32110 dated 07.11.2022 Rs.75000/-	Keeping in view the opinion of Legal Affairs Division, Registration Board granted renewal of registration w.e.f 19.01.2020 to 18.01.2025. The firm shall apply for the change of address as per Drug sale license in the concerned section and after approval of the aforesaid change the renewal letter shall be issued.

Remarks:

Extension in contract manufacturing was extended for next five years vide DRAP letter No. F.8-2/2015-Reg-III (M-248) dated 27.08.2015 w.e.f. **19.01.2015**.

Approval of change of address from M/s Amgomed Office No. 5 1st floor Rose Plaza I-8 Markaz Islamabad to M/s Amgomed Office No. 4, 1st Floor Ghousia Plaza Jinnah Avenue Blue Rea Islamabad is required.

Panel inspection of M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad dated 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 recommends renewal of DML and indicates Dry Powder Injection (General).

Decision of Renewal Sub Committee and Reply:
The application was deferred in 7th meeting of Renewal Sub Committee for opinion of Legal Affairs Disvion that whether application can be considered under Rule 27 of Drug (LR&A) Rules 1976 as application for extension in contract manufacturing was received after due date under the former contract manufacturing policy. The Disvion has now opined on the matter which is reproduced as under:

It is submitted that the subject cases have been evaluated in the light of latest Contract Manufacturing Policy and Rule 27 of the Drugs (LRA), Rules, 1976. Rule 27 of the Drugs (LRA) Rules, 1976 provides as follows:
Chapter,
*"**27. Duration of certificate of registration.** A certificate of registration under this shall unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration of the drug and may thereafter be renewed for periods not exceeding five years and a certificate to this effect shall be issued within one month at a time. Provided that an application **shall be made within Sixty days** after the expiry of the registration and when an application has been made as aforesaid the registration shall subject to the orders passed on the application for the renewal continue in force for the next period of five years"*
Moreover, in SRO 1347(I)/2021 (Contract Manufacturing Policy) the effects of Rule 27 shall mutatis mutandis applicable. Hence, in both instant cases, the fee was submitted well within period of 60 days after the expiry of the registration and fall in proviso clause of rule 27.
Moreover, the registration was granted to both the firms as per previous contract manufacturing policy and expired during enforcement of the previous policy. However, during the pendency of the renewal application, new contract manufacturing Policy promulgated on 15th October, 2021 vide SRO 1347(I)/2021. It is settled law that if during pendency of any application, the law/policy has been amended or changed then the pending application shall be processed in accordance with amended or new law/policy. Reliance is placed on judgment dated 11.05.2022 in CP No. 4425/2021 M/s Medisure Laboratories Vs FOP by Sindh High Court, Karachi. Therefore, in the light of above facts and position of the law, the applications of the firms may be processed accordingly.
Decision of the Board is mentioned against each case.

M/s Laderley Bio-Tech Pharma 240 Street 6, Phase 2 Gulraiz Colony Rawalpindi.

7.	072568	Zoletech Inj 40mg Each vial (lyophilized)contains Omeprazole Sodium 4.6mg eq to ……40mg **Contract Manufacturer:** M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad.	13.06.2013 Approval of import to local Mfg: **07.04.2016**	Rs.50000/-dated 15.04.2021	Keeping in view the opinion of Legal Affairs Division, Registration Board granted renewal of registration w.e.f 07.04.2021 to 06.04.2026

Decision of Renewal Sub Committee and Reply:
The application was deferred in 7th meeting of Renewal Sub Committee for opinion of Legal Affairs Disvion that whether application can be considered under Rule 27 of Drug (LR&A) Rules 1976 as application for extension in contract manufacturing was received after due date under the former contract manufacturing policy. The Disvion has now opined on the matter which is reproduced as under:

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been made as aforesaid the registration shall subject to the orders passed on the application for the renewal continue in force for the next period of five years"
Moreover, in SRO 1347(I)/2021 (Contract Manufacturing Policy) the effects of Rule 27 shall mutatis mutandis applicable. Hence, in both instant cases, the fee was submitted well within period of 60 days after the expiry of the registration and fall in proviso clause of rule 27.
Moreover, the registration was granted to both the firms as per previous contract manufacturing policy and expired during enforcement of the previous policy. However, during the pendency of the renewal application, new contract manufacturing Policy promulgated on 15th October, 2021 vide SRO 1347(I)/2021. It is settled law that if during pendency of any application, the law/policy has been amended or changed then the pending application shall be processed in accordance with amended or new law/policy. Reliance is placed on judgment dated 11.05.2022 in CP No. 4425/2021 M/s Medisure Laboratories Vs FOP by Sindh High Court, Karachi. Therefore, in the light of above facts and position of the law, the applications of the firms may be processed accordingly.
Decision of the Board is mentioned against each case.

Case No: 2 Renewal applications submitted after due date but within sixty days

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/s. Frontier Dextrose Limited, Plot No. 18/3 Phase-I Hattar Industrial Estate Hattar(DML No.000633)					
8.	003774-EX	FDL-DS 1/2 Infusion Each 100ml contains: Dextrose Anhydrous B.P…..5gm Sodium Chloride……0.45gm Water for injection ……QS	16-10-2012	Dy. No. 34879 dated 01-12-2022 Rs. 30000/-	Renewal is granted w.e.f 16.10.2022 to 15.10.2027
9.	003776-EX	FDL Ringer's (Infusion) Each 1000ml contains: Sodium Lactate……3.10gm Calcium Chloride dihydrate…...0.27gm Potassium Chloride…...0.40gm Sodium Chloride…….6gm Water for Injection ……q.s to make 1000ml	16-10-2012	Dy. No. 34880 dated 01-12-2022 Rs. 30000/-	Renewal is granted w.e.f 16.10.2022 to 15.10.2027
10.	049818	Sterifluid-5 Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose …..……5gm. (B.P Specs)	**16-07-2008** Change of BN: 24.09.2008	Rs.10000/- dated **26.08.2013** Rs. 10000/- dated 16.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.5264618291) Rs. 20000/- (Slip No.5709069592)	Renewal is granted w.e.f 16.07.2018 to 15.07.2023
11.	049819	Sterifluid-10 Infusion Each 100ml Contains:- Dextrose Monohydrate eq. to Anhydrous Dextrose …..……10gm. (B.P Specs)	**16-07-2008** Change of BN: 24.09.2008	Rs.10000/- dated **26.08.2013** Rs. 10000/- dated 16.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/-	Renewal is granted w.e.f 16.07.2018 to 15.07.2023

				dated 10.01.2023 (Slip No.63229266) Rs. 20000/- (Slip No.9998827102)	
12.	049285	Sterifluid-DS 1/2 Infusion Each 100ml Contains Dextrose Monohydrate eq. to Anhydrous Dextrose…5gm Sodium Chloride…0.45gm (B.P Specs)	09-07-2008 Change of BN: 24.09.2008	Rs.10000/- dated **26.08.2013** Rs. 10000/- dated 09.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.519433822592) Rs. 20000/- (Slip No.3268324595)	Renewal is granted w.e.f 09.08.2018 to 08.08.2023
13.	049286	Sterifluid- Peads Infusion Each 100ml Contains Dextrose Monohydrate eq. to Anhydrous Dextrose…4.3gm Sodium Chloride…0.18gm (B.P Specs)	**09-07-2008** Change of BN: 24.09.2008	Rs.10000/- dated **26.08.2013** Rs. 10000/- dated 09.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.7627840088) Rs. 20000/- (Slip No.0174775744)	Renewal is granted w.e.f 09.08.2018 to 08.08.2023
14.	052739	Sterifulid-RL Infusion Each 100ml contains: Sodium Lactate…..0.32gm Calcium Chloride Di-hydrate…..0.027gm Potassium Chloride…..0.04gm Sodium Chloride…..0.60gm (BP Specifications)	**04-11-2008** Correction of formulation dated 06.08.2009	Rs.10000/- dated 26.08.2013 Rs.10000/- dated **18.11.2018** Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.79540458)	Renewal is granted w.e.f 04.11.2018 to 03.11.2023
15.	052740	Sterifulid-RLD Infusion Each 100ml contains: Sodium Lactate…...0.31gm Calcium Chloride Di-hydrate…...0.027gm Potassium Chloride..0.04gm Sodium Chloride…...0.60gm Dextrose Anhydrous……5.0gm (BP Specifications)	04-11-2008	Rs.10000/- dated 26.08.2013 Rs.10000/- dated **18.11.2018** Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.11307988)	Renewal is granted w.e.f 04.11.2018 to 03.11.2023
16.	051074	Sterifulid-NS Infusion Each 100ml contains: Sodium Chloride……0.9gm (BP Specifications)	20.08.2008	Rs.10000/- dated **26.08.2013** Rs.10000/- dated 09.07.2018	Renewal is granted w.e.f 20.08.2018 to 19.08.2023

				Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.8203937070)	
17.	050860	Sterisol-DS Infusion Each 100ml contains Dextrose Monohydrate eq to or Anhydrous Dextrose……5.0gm Sodium Chloride……0.9gm (BP Specifications)	01.08.2008	Rs.10000/- dated **26.08.2013** Rs.10000/- dated 09.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.74906660)	Renewal is granted w.e.f 01.08.2018 to 31.07.2023
Decision of the Board is mentioned against each case.					

Additional Agenda of Import & Vet-I Section

Case No. 01: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following biological product approved in 321st meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug &Composition	Panel of Inspector(s)/ Date of inspection
1.	M/s. Brand Station, 69 Wocland Villas Lahore, Near Raiwind Road, Lahore./ **Manufacturer:** M/s. Yebio Bioengineering Co., Ltd Adress: No.260 Heyuan Road Hongdao, Qingdao, China.	Yevac ND vaccine 500ml Each dose (0.5ml) contains:- Newcastle Disease Virus Strain Lasota $\geq 10^{8.1}$ EID_{50} before inactivation	(i)Mr. Zafar Minhas, Deputy Director (NCLB), DRAP, Islamabad. (ii)Sadia Mehvish, Federal Inspector of Drugs, DRAP, Islamabad. **12-12-2022 & 21-12-2022**

Accordingly, an inspection was carried out by inspection panel dated 12-12-2022 & 21-12-2022 and final remarks of the panel are as under:-

Conclusion:-

The proceedings of the virtual inspection were adversely influenced by a slew of factors summarized below:

(a) Lack of provision for appropriate tools like cameras, bore scopes, fiberscope ete. By the manufacturer to carry out virtual inspection.
(b) Lack of provision of internet inside the production facility due to which production area could not be inspected.
(c) The videos of production area provided by the manufacturer were devoid of description, voiceovers, steps by step explanation of manufacturing process as well as the visuals of machinery in operation.
(d) Lack of readily available documents for review in English language with notarization or Embassy verification.
(e) Inadequacy of provided documents & videos as discussed in detail above.
(f) Non availability of key documents in English language lie veterinary Chinese Pharmacopoeia & Chinese guidelines from an independent source.
(g) Non compliance of sterile area monitoring practices & their frequencies in accordance with internationally accepted Guidelines.
(h) Lack of clarification regarding the equivalence of Chinese GMP standards with International

Guidelines & of Chines Veterinary Pharmacopeia with official books (BP), USP etc.) as mentioned in the Drugs Act, 1976 & DRAP Act, 2012.

Considering the facts mentioned above, the areas inspected, the people met an d the documents reviewed, and considering the findings of the inspection, the panel reached the conclusion that since manufacturing/production facility of the firm could not be viewed combined with deficiencies in the provided documents, it is not possible to ascertain basic vaccine manufacturing system or its compliance with GMP. It is therefore, strongly recommended that on-site inspection of the firm should be carried out before of registration of applied product i.e Yevac ND vaccine and the firm should be compelled/obligated to main & keep an English translation of relevant readily available for review on request.

Decision: Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendations. The division shall process the case before issuance of minutes of the meeting.

Miscellaneous Decision:

Registration Board while considering the registration applications decided to refer following points to QA& LT Division:

- GMP inspection of the new Manufacturing units must be carried out at least within a year of grant of the drug product registrations.
- During routine inspections being conducted for the sake of GMP or grant of renewal of DML, the panel shall also verify the product development and stability studies data submitted by the firm along with their registration applications.

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